

EPA REGISTRATION NUMBER 56783-1- Vol. 1

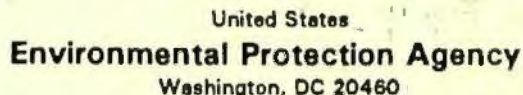
E.P.A. Reg. No.

56783-R

C.R.P.
Code

Event

Date of Application	Action Code	Record No. Ref. No.		Response Date	Response Code
10/20/86	175	183805	New APPLICATION - old chemical	2/28/87	39
09/15/1986	176	188,063	Resub. Storage Stability Data	6/22/87	38
3/21/87	176	197,955	Nonataf Data	6/20/87	38
5/28/87	176	196,942	Resubmission of Revised Labels	6/22/87	18
2-2-88	345	216658		7/28/88	17
6/28/88	300	227609		7/28/88	17
12/7/88	300	242160		11/28/89	13
3/12/92	455	419838	Enforcement Case Review	6/18/92	38
9/1/92	300	425828		10/29/92	12
4/26/93	300	440858		5/17/93	38
6-1-93	301	441900		6/16/93	38
8-18-94	300	472472	Updated Calculating for 9-1-95	8/9/94	17
3-15-96	300	504357	Calculating on existing stock	4-25-96	18
3-22-96	301	504362	" " (FAX)	4-25-96	18
4-30-96	301	527796		8-6-97	38



<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56783-1	2. EPA Product Manager GEORGE LARocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) EcoHEALTH, INC / DARMINIX	PM#	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02102 617 742 2400 Fax 617 742 4953 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☐ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated _____

☒ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application.

☒ Notification - Explain below. ☐ Other - Explain below.

NOTIFICATION
JAN 20 2004

Explanation Notification of Label change relative to PR Notice 2001-6. This notification is consistent with the guidance in PR Notice 2001-6 and the requirements of EPA's regulations at 40 CFR 156.10 and 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make false statements to EPA. I further understand that if this notification is not consistent with the guidance of PR Notice 2001-6 and the requirements of 40 CFR 156.10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt No. per container	
2. Type of Container					
<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____					
3. Location of Net Contents Information		4. Size(s) Retail Container		5. Location of Label Directions	
<input type="checkbox"/> Label <input type="checkbox"/> Container				<input type="checkbox"/> _____ <input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Alexander Kovel	Title PRESIDENT	Telephone No. (Include Area Code) 617 742 2400
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		B. Date Application Received (Stamped)
2. Signature Alex Kovel	3. Title PRESIDENT	Date Application Received (Stamped)
4. Typed Name ALEXANDER KOVEL	5. Date DEC 29, 2003	

ECOHEALTH, INC.

Monday, December 29, 2003

George LaRocca
US Environmental Protection Agency
Pesticide Programs (7504C)
Document Processing Desk (AMEND)
401 M Street S.W.
Washington, DC 20460-0001

Re: 56783-1 (Damminix) and 56783-2 (Mite Arrest)

Dear Mr. LaRocca,

I am sending you under separate cover three different items:

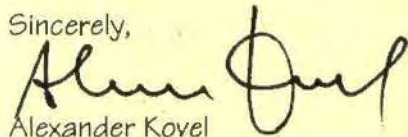
- ✓ • two Notifications, (one for each of the above pesticides, 56783-1 and 56783-2, under PR Notice 2001-6), and
- one Amendment of the label for 56783-2, required by PR Notice 2001-1.

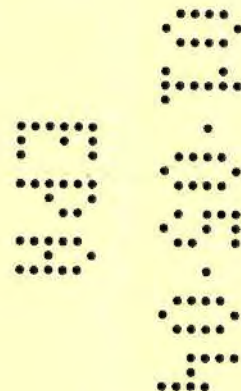
No Amendment for 56783-1 under PR Notice 2001-1 is required, since one was accepted by EPA on January 16, 2002. Unfortunately, at that time I simply overlooked the requirement to file the same First Aid label amendment for 56783-2. Hence, I am enclosing it at this time.

You were very kind to answer my questions on the phone last week, and I hope I have submitted these various applications correctly. If anything else is needed or corrections are required, I will be very pleased to send them immediately.

Thank you very much.

Sincerely,


Alexander Kovel





DAMMINIX®

TICK Tubes

USE AS AN AID IN THE
CONTROL OF LYME
DISEASE CARRYING TICKS

24 TUBES • TREATS APPROXIMATELY 22,000 SQ. FT.

TREATS
22,000

DAMMINIX® A TICK TOXICANT As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA1

ACTIVE INGREDIENT: +* Permethrin 7.4%

INERT INGREDIENTS: 92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2 dichloroethenyl)2, 2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

CAUTION: KEEP OUT OF REACH OF CHILDREN

FIRST AID

INGESTION - If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

EXPOSURE, SKIN IRRITATION - If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

EYES - If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding the woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed. The tubes and unused cotton are biodegradable and may be left in the application site.

STORAGE: Store at room temperature. Do not contaminate water, food or feed by storage.

DISPOSAL: If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-800-234-8425 for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS: Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS: This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by disposal of wastes or equipment washwaters.

© 2004, ECOHEALTH, INC. 33 MT. VERNON ST., BOSTON, MASSACHUSETTS 02108 617-742-2400 CONTENTS: 24 Damminix Tubes, each containing 4.5 grams.

NOTIFICATION

JAN 20 2004

Actual Size

Mr. Alexander Kovel
Eco Health, Inc.
33 Mount Vernon Street
Boston, MA 02108

JAN 18 2002

Dear Mr. Kovel

Subject: Amendment- update label for PR Notice 2001-6
Damminix Tick Tubes
EPA Registration No. 56783-1
Your submission dated October 15, 2001

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, and a copy of a stamped label is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

Sig,

The labels came melted.
I put them in the CSF folder.
I copied one of them. If you need
more use the ones in the CSF.

The registration said he has no
more labels available.

DAMMINIX® A TICK TOXICANT As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA1

ACTIVE INGREDIENT: +- Permethrin

7.4%

INERT INGREDIENTS:-----

92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (1+/-) cis/trans 3-(2,2-dichloroethenyl) 2, 2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

CAUTION: KEEP OUT OF REACH OF CHILDREN

FIRST AID

INGESTION - If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

EXPOSURE, SKIN IRRITATION - If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

EYES - If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
 - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
 - Call a poison control center or doctor for treatment advice.
- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY: For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding the woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed.

STORAGE AND DISPOSAL: Store at room temperature. Do not contaminate water, food or feed by storage and disposal. Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS: Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS: This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by disposal of wastes or equipment washwaters.

© 2001, ECOHEALTH, INC. 33 MT. VERNON ST., BOSTON, MASSACHUSETTS 02108

617-742-2400 CONTENTS: 24 Damminix Tubes, each containing 4.5 grams.

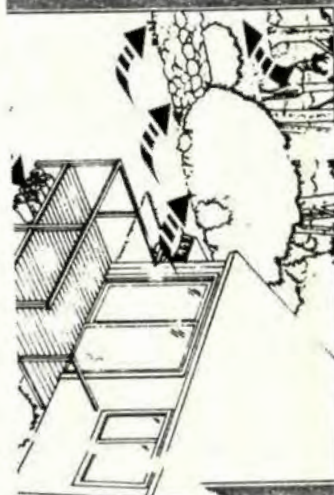
USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under
EPA Reg. No. 56783-1

JAN 16 2002

ACCEPTED

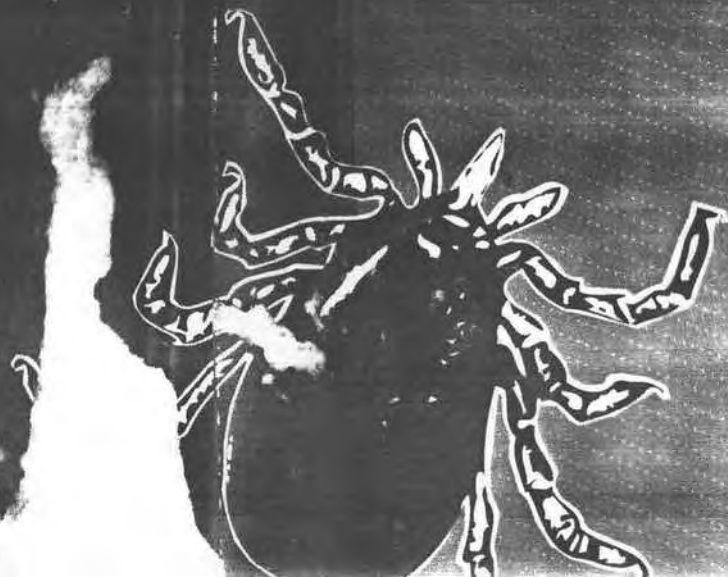


Easy to use.
Apply once in the
spring and once in
the summer.

DAMMINIX[®]

USE AS AN AID
IN THE CONTROL
OF LYME DISEASE
CARRYING TICKS

Tubes



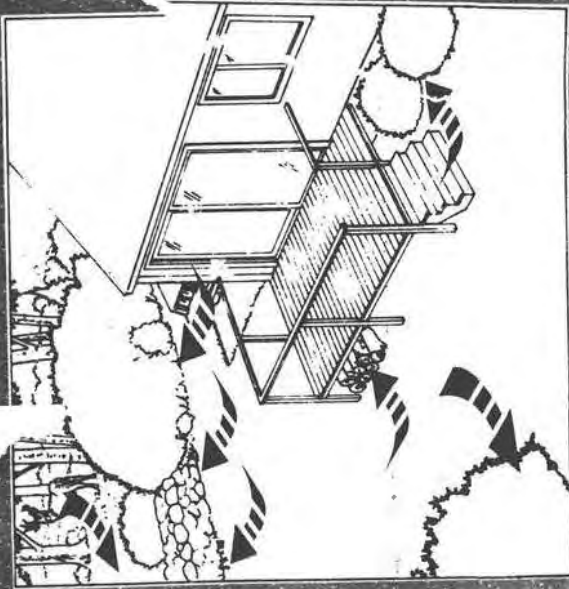
TICK

Tubes

USE AS AN AID IN THE
CONTROL OF LYME
DISEASE CARRYING TICKS

DAMMINIX[®]

Tick Tubes

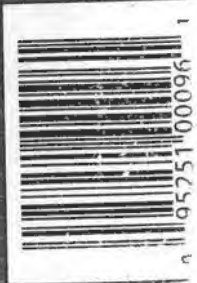


Easy to use.
Apply once in the
spring and once in
the summer.

Place in brush, wooded areas, walls
and flower beds. Do not use of larvae
most ticks do not live or lay.

USE AS AN AID IN THE CONTROL OF LYME DISEASE CARRYING TICKS.

Tick Tubes



Tick Tubes

7-742-2400 CON

HAZARDS TO HUMANS:
Irritating sensations. Wash
thoroughly. Environmental hazard.
Where surface water is present,
equipment washwaters.

STORAGE AND DISPOSAL:
Store in original container. Do not
use tubes and unused contents.

Precautions:
Do not use if the feeding activity is
completely removed.

FOR TREATMENT OF WOODLOTS:
Place in any direction. For control
of ticks within the woodlot.

FOR TREATMENT OF WOODLOTS:
Wherever mice may reside,
they could be treated.

A B

ECOHEALTH, INC.

Monday, October 15, 2001

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504-C)
US Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: Damminix Tick Tubes , #56783-1

Dear Sirs,

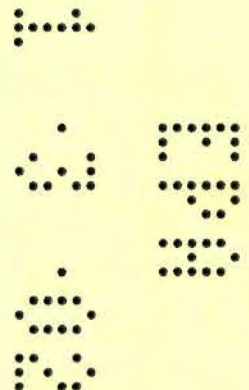
Please find enclosed the amended label for the above product containing the new first aid language.

Thank you.

Sincerely,



Alexander Kovel





Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

288347

Application for Pesticide - Section I

1. Company/Product Number 56783-1	2. EPA Product Manager GEORGE LAROCCA	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) EcoHealth, Inc./DAMMIX Ticks	PM# 03	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108 617 742 2400 Fax 617 742 4953	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

☐ Check if this is a new address

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

As per PR Notice 2001-1 re First AD STATEMENTS

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name ALEXANDER KOVEL	Title PRESIDENT	Telephone No. (Include Area Code) 617 742 2400
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title PRESIDENT	
4. Typed Name Alexander Kovel 33 Mt. Vernon St. Boston, MA 02108	5. Date Oct 15, 2001	



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

288347

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature	3. Title	
4. Typed Name	5. Date	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

288347

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted					
If "Yes" Unit Packaging wgt. _____ No. per container _____		If "Yes" Package wgt. _____ No. per container _____			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name		Title		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature		3. Title			
4. Typed Name		5. Date			

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.61 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

APR 10 2000

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Alexander Kovel
EcoHealth, Inc.
33 Mt. Vernon Street
Boston, Massachusetts 02108

Dear Mr. Kovel:

Subject: Current Labeling on Existing Stocks
Damminix
EPA Registration No. 56783-1

Your product was identified in a recent walk through in a local retail store. It was observed that a portion of the required language to be included on the front panel of a pesticide product, is located on the bottom panel of the rectangular box enclosure on the above referenced product. It is mandatory that the following information be included on the front panel of a registered pesticide: ingredient statement; signal word; skull and crossbones (if required); child hazard warning; EPA Registration No.; RESTRICTED USE PESTICIDE; (if so classified) and a reference to the location of other precautions.

You must revise your labeling such that when your product is displayed, all the required information on the front panel is immediately visible to the consumer. Please submit this revised labeling at the next label printing.

If you have any questions regarding this letter, please contact Linda Werrell, of my staff, at 703-308-8033.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda Werrell" followed by a horizontal line.

George T. LaRocca
Product Manager (13)
Insecticide Branch

Registration Division (7505C)

AUG - 6 1997

Mr. Alexander Kovel
EcoHealth, Inc.
33 Mt. Vernon Street
Boston, Massachusetts 02108

Dear Mr. Kovel:

Subject: Labeling on Existing Stocks and Updated Labeling; Final Printed Labeling
Damminix
EPA Registration No. 56783-1
Your Submission Dated April 30, 1996

In an Agency letter dated April 25, 1996 we requested that you replace (on the tube label only) "Keep Out of Reach of Children" with "Do Not Allow Children or Pets to Handle or Play with this Product." This change in precautionary wording is for products (including pet collars, certain bait stations, etc.) with a use pattern/delivery mechanism that make "Keep Out of Reach of Children" an impractical statement. For example, your product is placed in yards around homes where children and pets may have access to them.

The reason we accepted your tube labeling without comment in our August 29, 1995 letter was that this new policy was not in place. Please submit new tube labeling to the Agency, with the requested labeling change.

Sincerely,

George T. LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

Resubmission JH

ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . for control of Lyme Disease carrying ticks.

Tuesday, April 30, 1996

George T. LaRocca
Product Manager, Insecticide Rodenticide Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
401 M Street NW
Washington DC 20460

301/527796
38

Re: Damminix. EPA Reg. # 56783-1

Dear Mr. LaRocca,

I have just received your letter of April 25¹ in which you deal with several separate labelling matters concerning Damminix. Your paragraph 2 concerns two items:

a) the language on the package as to "how Damminix Tick tubes kill ticks ...". We have no problem with your decision that this needs to be overstickered until you have had a chance to review the content, since we have already overstickered all boxes to obscure the offending language. Moreover, the error is clearly ours and although we wish we had your acceptance of this language, we did not give you enough time to consider it and it is not necessary for this season.

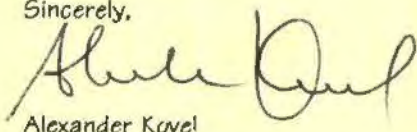
b) the shipments to Fire Island. We thank you for your extension of time to use the old labelling.

As to your paragraph 1 concerning the new tube language itself, we seem to be working from different records, which I very much hope is not the case.

When I took over direction of this company in at the end of 1995, Fred DeFinis gave me your correspondence of August 29, 1994, with its enclosed stamped accepted tube labelling, as the governing requirement in producing the new package and tube labelling. Since then I have not seen any other item in our files that varies the terms of that correspondence. Therefore, in producing the new packaging for this season I worked from that August 29 correspondence, a copy of which is enclosed with this letter. At all points I was particularly careful to exactly track what I thought to be the required language. The submitted and accepted tube language in that correspondence says "Keep out of reach of children". Moreover, on page one of that letter, in the last paragraph, referring to a copy of the tube text, it says "Labelling for the Damminix tube is acceptable".

I don't see what our mistake could have been, unless there was some later stamped amendment of the tube labelling of which I am not aware. That would be terrible. I would be very sorry if that is the case and we would then do what we can to conform. Can you please advise and I am sure we can resolve this. Thank you.

Sincerely,


Alexander Kovel

¹ Your letter consisted of enclosures and only one page of text, ending with the words "plus above comments.", without a signature page. I assume that the signature page was inadvertently omitted and did not contain any additional comments on pages after page one to which we need to respond. Please let me know.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 29 1994

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Mr. Fred DeFinis
Ecohealth, Inc.
110 Broad Street
Boston, MA 02110

Dear Mr. DeFinis:

Subject: Labeling on Existing Stocks and Updated Labeling
Damminix
EPA Registration No. 56783-1
Your Letter Dated August 18, 1994

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable, provided that you make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

1. Revise Environmental Hazards as follows:

"This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by disposal of wastes or equipment washwaters."

The statement (by itself) "Do not apply directly to water" is appropriate for products that are residential use only.

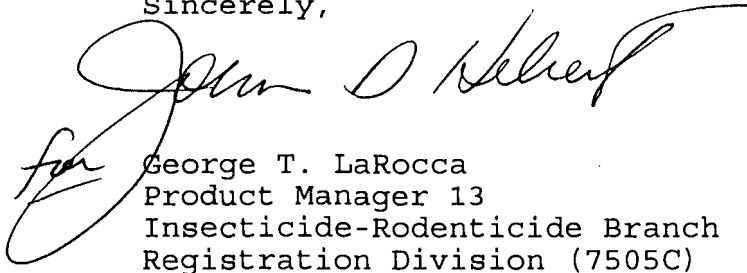
2. Your product contains only one active ingredient. Make the term Active Ingredients singular. (Refer to PR Notice 93-8).

Labeling for the Damminix tube is acceptable. With respect to your request to use existing labeling until August 31, 1995, we agree to allow the conditional marketing of Damminix in its current package and labeling submitted September 1, 1992 through August 31, 1995. It is understood that after September 1, 1995 all product packaged and shipped will carry the labeling submitted with the subject letter plus above comments.

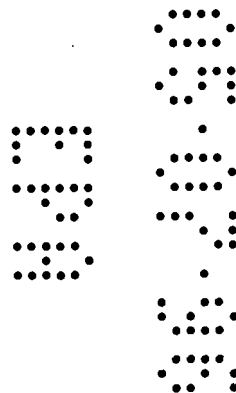


Submit three copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

Sincerely,


George T. LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

enclosure



Damminix Carton Label (proposed)

DAMMINIX

A TICK TOXICANT As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA1

ACTIVE INGREDIENTS:

+* Permethrin 7.4%

INERT INGREDIENTS:

..... 92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2 dichloroethyl)2,
2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

CAUTION: KEEP OUT OF REACH OF CHILDREN

Statement of Practical Treatment

IF SWALLOWED—Contact a physician or Poison Control Center immediately.

IF ON SKIN—Remove contaminated clothing and wash affected areas with soap and water.

IF IN EYES—Flush with plenty of water. Call a physician if irritation persists.

DIRECTIONS FOR USE:...

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed.

STORAGE AND DISPOSAL:

Store at room temperature. Do not contaminate water, food or feed by storage and disposal.

Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water. Do not contaminate water by disposal of wastes or cleaning of equipment.

ACCEPTED
with COMMENTS
in EPA Label Order

ECOFHEALTH, INC.
AUG 29 1994

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

56783-1

CONTENTS:
24 DAMMINIX TUBES
each containing 4.5 grams

DAMMINIX TUBE LABEL (PROPOSED)

Damminix

ACTIVE INGREDIENTS:

+* Permethrin7.4%

INERT INGREDIENTS:

.....92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2 dichloroethyl)2,
2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

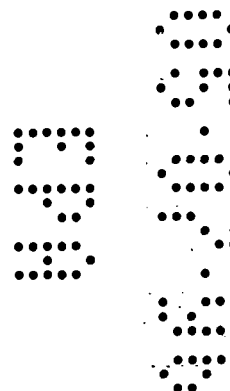
CAUTION: KEEP OUT OF REACH OF CHILDREN

See outer carton for complete directions and precautions

Net contents: 4.5 grams.

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

3015504362
3015504357
18/9

25 APR 1996

Mr. Alexander Kovel
EcoHealth, Inc.
33 Mt. Vernon St.
Boston, MA 02108

Dear Mr. Kovel:

Subject: Labeling on Existing Stocks and Updated Labeling
Damminix
EPA Registration No. 56783-1
Your Submissions Dated March 15, March 22, 1996

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, provided that you make the labeling changes listed below before your release the product for shipment bearing the amended labeling:

1. On the tubelabel replace the "Keep Out of Reach of Children" with "Do not allow Children or Pets to Handle or Play with this Product." Note that this change is for the tube label only. This was also brought to your attention in previous correspondence.
2. A review of our files does not indicate approval (stamped label) of the paragraph beginning How Damminix Tick Tubes Kill Ticks... Therefore we agree with New York State that this passage must be deleted or overstickered until we have had the opportunity to review this language against the data submitted. We will notify you when review is complete but it may take several months.

With respect to your request for an extension of time to use existing labeling we agree to allow the marketing of the old box and tube labels (without stickers) submitted September 1, 1992 through August 31, 1996. It is understood that this permission is for 500 boxes of 24 tubes and 160 boxes of 96 tubes for shipment to Fire Island only. It is understood that all product packaged and shipped after August 31, 1996 will carry the labeling submitted with the subject letter plus above comments.

CONCURRENCES

SYMBOL							
SURNAME	<i>Helen</i>						
DATE							

Submit three copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

DAMMINIX®
A TICK TOXICANT

**Tick
Tube**

ACTIVE INGREDIENT:	† *Permethrin, 7.4%
INERT INGREDIENTS:	92.6%
Total	100.0%

+ (3-phenoxphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethenyl)-2,4-dimethylcyclopropanecarboxylate.
* Cis/trans ratio: Min. 75% (+/-) cis and max. 65% (+/-) trans.

CAUTION: KEEP OUT OF REACH OF CHILDREN

See outer carton for complete directions and precautions.

Net Contents: 4.5 grams

EPA Reg. No. 56783-1 EPA Est. No. 5693 MA 1 U.S. Patent No. 4,662,104

ECOHEALTH, INC. BOSTON, MA 02106-2147

ACCEPTED
with COMMENTS
in EPA Letter Dated

25 APR 1996

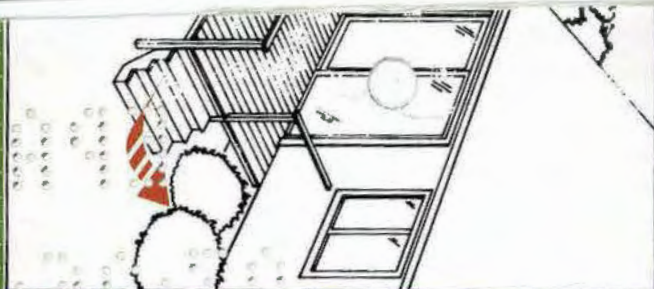
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

56783-1



**USE AS AN AID
IN THE CONTROL
OF LYME DISEASE
CARRYING TICKS.**

**DAMI
A TICK**



Easy to use.
Apply once in the
spring and once in
the summer.

Place in brush, woodpiles, rock walls
and flower-beds. Do not treat lawns -
most ticks do not live on lawns.

LYME DISEASE CARRYING TICKS.

USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

Tick Tubes

U.S. Patent No. 4,662,104
ACTIVE INGREDIENT: Permethrin, 7.4%

EPA Reg. No. 56783-1
EPA Est. No. 5693 MA-1



DAMMINIX® A TICK TOXICANT

U.S. Patent No. 4,662,104
ACTIVE INGREDIENT: Permethrin, 7.4%

Ti Tub

TREATS APPROXIMATELY
22,000 SQUARE FEET

24 TUBES • TREATS APPROXIMATELY
22,000 SQUARE FEET

DAMMINIX® A TICK TOXICANT As an aid in the control of ticks (that may carry Lyme Disease) the

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA-1

ACTIVE INGREDIENT:

+* Permethrin

7.4%

INERT INGREDIENTS:

92.6%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate.
Total 100.0%

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

CAUTION: KEEP OUT OF REACH OF CHILDREN

Statement of Practical Treatment

IF SWALLOWED - Contact a physician or Poison Control Center immediately.

IF ON SKIN - Remove contaminated clothing and wash affected areas with soap and water.

IF IN EYES - Flush with plenty of water. Call a physician if irritation persists.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should

USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

GK TICK TUBES

USE AS AN AID IN THE
CONTROL OF LYME
DISEASE CARRYING TICKS.

EPA Reg. No. 55783-1
EPA Est. No. 5693 MA 1

How Damminix® Tick Tubes kill ticks:

Deer ticks become carriers of Lyme disease by feeding on mice. Damminix tubes contain cotton nesting material impregnated with permethrin. The mice collect the cotton to make nests; the permethrin on the cotton kills the ticks without hurting the mice. Tests show that Damminix tubes are up to 97% effective against infected deer ticks.

OXIMATELY 22,000 SQ. FT.

infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

posed so that mice have access to the open ends. Product works best if not covered by leaves or other material.

TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 feet surrounding the yard area to be protected should be treated.

TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding the woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes also be replaced when nesting material is completely removed.

DRAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal. Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Irritant to eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

Product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by disposal of tubes or equipment washwaters.

47 617-742-2400 CONTENTS: 24 Damminix Tubes, each containing 4.5 grams.

TREATS APPROXIMATELY
22,000 SQUARE FEET

LITHO GUIDE

LITHO GRIPPER

DAMMINIX®
A TICK TOXICANT

USE AS AN AID
IN THE CONTROL
OF LYME DISEASE
CARRYING TICKS.

Tick
Tubes



USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

Tick
Tubes



DAMMINIX®
A TICK TOXICANT

Tick
Tubes

USE AS AN AID
IN THE CONTROL
OF LYME DISEASE
CARRYING TICKS.

U.S. Patent No. 4,662,104
ACTIVE INGREDIENT: Permethrin, 7.4%

EPA Reg. No. 56783-1
EPA Est. No. 5693 MA 1

U.S. Patent No. 4,662,104
ACTIVE INGREDIENT: Permethrin, 7.4%

EPA Reg. No. 56783-1
EPA Est. No. 5693 MA 1

TREATS APPROXIMATELY
5,500 SQUARE FEET

6 TUBES • TREATS APPROXIMATELY 5,500 SQ. FT.

→ CORR →

→ CORR →



USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

Tick Tubes

How Damminix® Tick Tubes kill ticks:
Deer ticks become carriers of Lyme disease by feeding on mice. Damminix tubes contain cotton nesting material impregnated with permethrin. The mice collect the cotton to make nests; the permethrin on the cotton kills the ticks without hurting the mice. Tests show that Damminix tubes are up to 97% effective against infected deer ticks.



Tick Tubes



Easy to use.
Apply once in the spring
and once in the summer.

Place in brush, woodpiles, rock walls and flower-beds.
Do not treat lawns - most ticks do not live on lawns.

TREATS APPROXIMATELY
5,500 SQUARE FEET

USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

DAMMINIX® A TICK TOXICANT As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

EPA Reg. No. 56783-1	EPA Est. No. 5693 MA1
ACTIVE INGREDIENT:	
+* Permethrin	7.4%
INERT INGREDIENTS:	92.6%
	Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethyl) 2,2-dimethylcyclopropanecarboxylate.
* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

CAUTION: KEEP OUT OF REACH OF CHILDREN
Statement of Practical Treatment
IF SWALLOWED - Contact a physician or Poison Control Center immediately.
IF ON SKIN - Remove contaminated clothing and wash affected areas with soap and water.
IF IN EYES - Flush with plenty of water. Call a physician if irritation persists.

DIRECTIONS FOR USE:
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses. For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding the woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

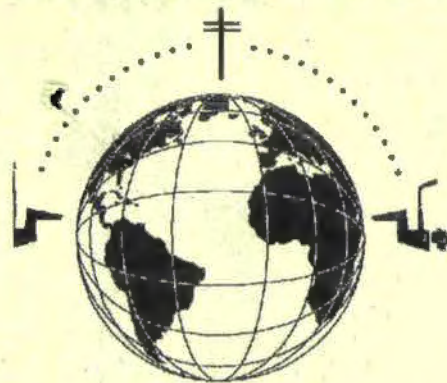
Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed.

STORAGE AND DISPOSAL:
Store at room temperature. Do not contaminate water, food or feed by storage and disposal. Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS
This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by disposal of wastes or equipment washwaters.





RapidFax

*This Fax was sent using FAXcilitate
The Premier Fax Software for the Apple Macintosh™*

To: George LaRocca, - Environmental Protection Agency

Date: 22 Mar 1996, • 16:05

Transmitting (2) pages, including cover sheet.

Note:

Friday, March 22, 1996, 16:04 pm

George T. LaRocca
Product Manager, Insecticide/Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Damminix. EPA Reg. # 56783-1

Also Via Fax 703 305 6596

Dear Mr. LaRocca,

Earlier today I sent you a letter concerning the shipment of boxes to Fire Island. This second letter concerns only the end panel language on our box.

As I mentioned to you, New York state only accepted the package label of our boxes of 6 and 24 for registration with a proviso that we add certain stickers to cover over language now appearing on the end panels, which reads as follows:

"How Damminix Tick Tubes kill ticks: Deer ticks become carriers of Lyme disease by feeding on mice. Damminix tubes contain cotton nesting material impregnated with permethrin. The mice collect the cotton to make nests; the permethrin on the cotton kills the ticks without hurting the mice. Tests show that Damminix tubes are up to 97% effective against infected deer ticks"

New York asserts that this language is not consistent with our EPA accepted label. I suggested that it is consistent, in that essentially the same language, never objected to by your office, or by New York or any state, was contained on our old package. Whether I am right or not, New York said that they had no discretion: we would have to sticker over the offending language and delete it from the next printing. Since there is no time to reprint labels and repack the boxes for this spring season, I agreed to do both, but asked if they had any objection to my enquiring of EPA if there was a less disruptive solution. They did say that they would abide by an EPA ruling but only if a stamped label amendment accepting this wording can be forthcoming from your office.

Needless to say, we would prefer not to have to go through the delay and expense of stickering, especially for an item that is as well known as Damminix and where the offensive language has been part of the package label for so long. If required to do so we will sticker the end panel, and we will also delete it for the next printing, but we would very much appreciate it if you could accept this as a label amendment if that is the proper course of action, so we do not have to do this.

If you accept this amendment, it would be enormously appreciated if a stamped or signed indication of your acceptance can be put on this letter or on some other form and sent back to us as soon as possible, so I can send it on to New York. I am extremely sorry about the short notice, but we are shipping product next week and of course we would like to avoid stickering the end panels.

Please call me if you have any questions, and thank you once again for your help.

Sincerely,

Alexander Kovel



RapidFax

*This Fax was sent using FAXcilitate
The Premier Fax Software for the Apple Macintosh™*

To: George LaRocca, - Environmental Protection Agency

Date: 22 Mar 1996, • 15:26

Transmitting (2) pages, including cover sheet.

Note:

Also Via Fax 703 305 6596

Friday, March 22, 1996, 15:25 pm

George T. LaRocca
Product Manager, Insecticide Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Damminix. EPA Reg. # 56783-1

Dear Mr. LaRocca,

I am sending this letter to confirm our conversation this morning as to the shipment of Damminix to Fire Island this season. As we discussed, instead of affixing the environmental hazard stickers we had discussed last week, you would prefer that we use the old box, including the old tubes, for this limited period and area.

It is understood that permission to ship the old boxes and old tubes without stickers will apply only to this season, not beyond August 31, 1996, and only to Fire Island. Last week I estimated the count to be in the range of 400-500 boxes. It now turns out, after an exact count, that there are 500 boxes of 24 tubes, and 160 boxes of 96 tubes each.

Thank you very much for this suggestion and your help.

Sincerely,

Alexander Kovel

Ecohealth, Inc.
33 Mt. Vernon Street, Boston, MA 02108 617 742 2400, fax 617 742 4953



United States
Environmental Protection Agency
Washington, DC 20460

☐
☒
☐

Registration
Amendment
Other

OPP Identifier Number

244238

Application for Pesticide - Section I

1. Company/Product Number Ecohealth, Inc./56783-1	2. EPA Product Manager George LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Ecohealth, Inc./Damminix	PM#	
5. Name and Address of Applicant (Include ZIP Code) Ecohealth, Inc. 33 Mt. Vernon Street Boston, MA 02108 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 56783-1 Product Name Damminix	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

The name "Damminix" is being modified to read additionally as "Damminix a Tick Toxicant. Tick Tubes"

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 6 Tube container and 24 Tube container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Alexander Kovel		Title President	
		Telephone No. (Include Area Code) 617 742 2400	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 37
2. Signature 		3. Title President	
4. Typed Name Alexander Kovel		5. Date April 5, 1996	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . for control of Lyme Disease carrying ticks.

Friday, April 5, 1996

George T. LaRocca
Product Manager, Insecticide Rodenticide Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
401 M Street NW
Washington DC 20460

Re: Damminix. EPA Reg. # 56783-1

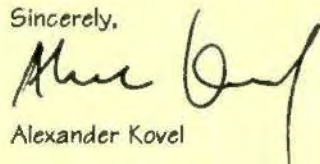
Dear Mr. LaRocca,

Please find two letters that I misaddressed by sending them directly to Jefferson Davis Highway, and which were returned to me last week, and a notification of minor label change concerning the name Damminix. As the notice states, we are adding the name "A tick toxicant - Tick Tubes" to the name Damminix.

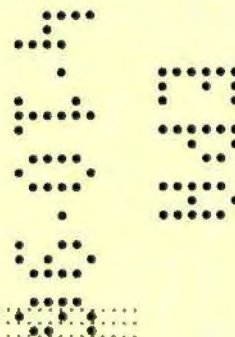
John Hebert of your office was very helpful. Please thank him for me.

Thank you.

Sincerely,



Alexander Kovel



ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . for control of Lyme Disease carrying ticks.

Also Via Fax 703 305 6596

Friday, March 22, 1996, 12:49 pm

George T. LaRocca
Product Manager, Insecticide Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Damminix. EPA Reg. # 56783-1

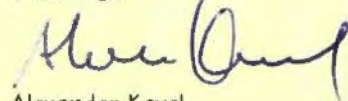
Dear Mr. LaRocca,

I am sending this letter to confirm our conversation this morning as to the shipment of Damminix to Fire Island this season. As we discussed, instead of affixing the environmental hazard stickers we had discussed last week, you would prefer that we use the old box, including the old tubes, for this limited period and area.

It is understood that permission to ship the old boxes and old tubes without stickers will apply only to this season, not beyond August 31, 1996, and only to Fire Island. Last week I estimated the count to be in the range of 400-500 boxes. It now turns out, after an exact count, that there are 500 boxes of 24 tubes, and 160 boxes of 96 tubes each.

Thank you very much for this suggestion and your help.

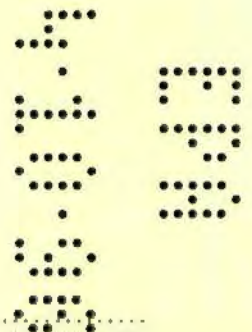
Sincerely,



Alexander Kovel

Ecohealth, Inc.
33 Mt. Vernon Street, Boston, MA 02108 617 742 2400, fax 617 742 4953

ORIGINALLY
RETURNED
AS
UNADDRESSED



ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . for control of Lyme Disease carrying ticks.

Friday, March 22, 1996, 16:04 pm

George T. LaRocca
Product Manager, Insecticide Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Damminix. EPA Reg. # 56783-1

Also Via Fax 703 305 6596

Dear Mr. LaRocca,

Earlier today I sent you a letter concerning the shipment of boxes to Fire Island. This second letter concerns only the end panel language on our box.

As I mentioned to you, New York state only accepted the package label of our boxes of 6 and 24 for registration with a proviso that we add certain stickers to cover over language now appearing on the end panels, which reads as follows:

"How Damminix Tick Tubes kill ticks: Deer ticks become carriers of Lyme disease by feeding on mice. Damminix tubes contain cotton nesting material impregnated with permethrin. The mice collect the cotton to make nests; the permethrin on the cotton kills the ticks without hurting the mice. Tests show that Damminix tubes are up to 97% effective against infected deer ticks"

New York asserts that this language is not consistent with our EPA accepted label. I suggested that it is consistent, in that essentially the same language, never objected to by your office, or by New York or any state, was contained on our old package. Whether I am right or not, New York said that they had no discretion: we would have to sticker over the offending language and delete it from the next printing. Since there is no time to reprint labels and repack the boxes for this spring season, I agreed to do both, but asked if they had any objection to my enquiring of EPA if there was a less disruptive solution. They did say that they would abide by an EPA ruling but only if a stamped label amendment accepting this wording can be forthcoming from your office.

Needless to say, we would prefer not to have to go through the delay and expense of stickering, especially for an item that is as well known as Damminix and where the offensive language has been part of the package label for so long. If required to do so we will sticker the end panel, and we will also delete it for the next printing, but we would very much appreciate it if you could accept this as a label amendment if that is the proper course of action, so we do not have to do this.

If you accept this amendment, it would be enormously appreciated if a stamped or signed indication of your acceptance can be put on this letter or on some other form and sent back to us as soon as possible, so I can send it on to New York. I am extremely sorry about the short notice, but we are shipping product next week and of course we would like to avoid stickering the end panels.

Please call me if you have any questions, and thank you once again for your help.

Sincerely,


Alexander Kovel

ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . ~~for control of~~ Lyme Disease carrying ticks.

JH
Pull packed and
return to me

Friday, March 15, 1996

George T. LaRocca
Product Manager, Insecticide Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Damminix. EPA Reg. # 56783-1

Dear Mr. LaRocca,

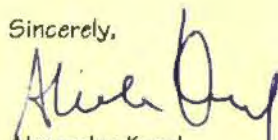
Please find enclosed three sets of the new printed labels we have made for our boxes of 24 and 6 tubes. The box of 96 label is unchanged, except that, as with the subject of my fax to you last week pertaining to the old boxes of 24, it will have opaque tape covering the reference to "control of" in the title, and it will bear a sticker as follows:

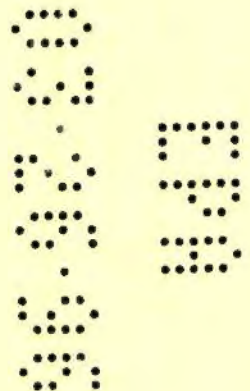
Precautionary statement:

Environmental Hazards: This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

Thank you.

Sincerely,


Alexander Kovel



ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . for *Lyme Disease carrying ticks.*

Also Via Fax 703 305 6596

Thursday, March 14, 1996, 16:20 pm

George T. LaRocca
Product Manager, Insecticide Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
Washington, D.C. 20460

Re: Damminix. EPA Reg. # 56783-1

Dear Mr. LaRocca,

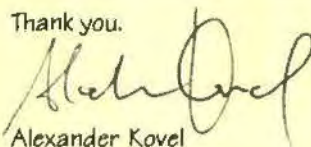
Thank you very much for being available this afternoon by telephone. By now you will have received the fax that I sent you earlier today. I am happy to make the changes you suggested. We are getting a final count in the warehouse now, but I estimate the total number of old boxes to be between 400 and 500, of which 370 will ship to Fire Island Pines. We will now do two things to each of the old boxes that we ship:

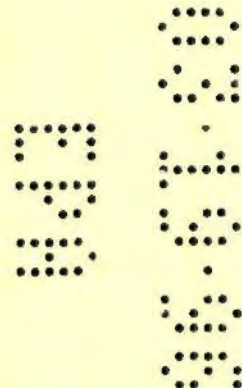
- (1) We will put a piece of opaque tape over the front and the end labels of each box where it says "for control of Lyme disease carrying ticks", so that at least the word "control" is obscured; and
- (2) we will affix to a blank space on the box an additional sticker that reads:

Precautionary statement:

Environmental Hazards: This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

Thank you.


Alexander Kovel



3/22/96

Note to File

In response to the attached fax's and hard copy from EcoHealth and there request to overstocker existing ~~stock~~ off label stock I agreed it would be easier and less label clutter to just have them request additional time to use up small quantity (320 boxes) of product that will be shipped to Fire Island Pines. The differences in labeling are not significant ~~was~~ ~~from~~ from a human or environmental hazard standpoint and do not warrant immediate overstocking. EcoHealth will formally submit request to use up this additional existing stock

Georg Labovay

03.15.96



RapidFax

*This Fax was sent using FAXcilitate
The Premier Fax Software for the Apple Macintosh™*

To: George LaRocca, - Environmental Protection Agency

Date: 18 Mar 1996, • 15:08

Transmitting (2) pages, including cover sheet.

Note:

Also Via Fax 703 305 6596

Monday, March 18, 1996, 14:59 pm

George T. LaRocca
Product Manager, Insecticide Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Damminix. EPA Reg. # 56783-1

Dear Mr. LaRocca,

Pursuant to our conversation last week, I want to confirm to you that the old Damminix boxes we will be shipping to Fire Island, with the additional stickers referred to in my fax/letter of March 14, contain the pre-1995 Damminix tubes.

Thank you.

Sincerely,

Alexander Kovel

Ecohealth Inc.
33 Mt Vernon Street, Boston, MA 02108,
Telephone: 617 742 2400, Fax 617 742 4953

Also Via Fax 703 305 6596

Monday, March 18, 1996, 14:59 pm

George T. LaRocca
Product Manager, Insecticide Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Damminix. EPA Reg. # 56783-1

Dear Mr. LaRocca,

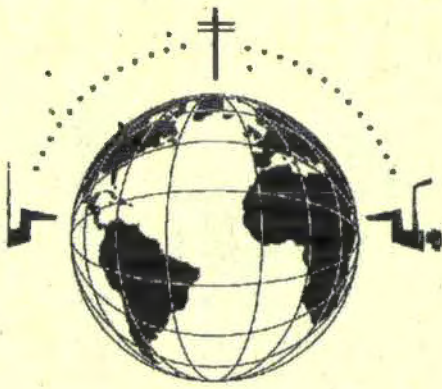
Pursuant to our conversation last week, I want to confirm to you that the old Damminix boxes we will be shipping to Fire Island, with the additional stickers referred to in my fax/letter of March 14, contain the pre-1995 Damminix tubes.

Thank you very much for your help.

Sincerely,

Alexander Kovel

Ecohealth Inc.
33 Mt Vernon Street, Boston, MA 02108,
Telephone: 617 742 2400, Fax 617 742 4953



RapidFax

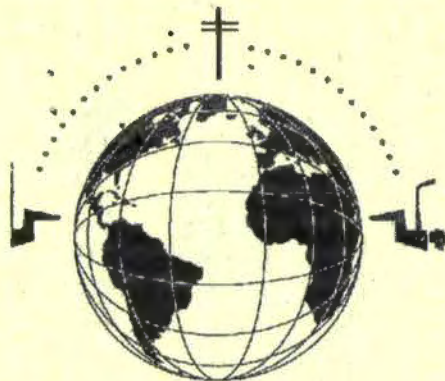
*This Fax was sent using FAXcilitate
The Premier Fax Software for the Apple Macintosh™*

To: George LaRocca, - Environmental Protection Agency

Date: 14 Mar 1996, • 13:08

Transmitting (2) pages, including cover sheet.

Note:



RapidFax

*This Fax was sent using FAXcilitate
The Premier Fax Software for the Apple Macintosh™*

To: George LaRocca, - Environmental Protection Agency

Date: 14 Mar 1996, • 16:22

Transmitting (2) pages, including cover sheet.

Note:

ViaFax 703 305 6596

Thursday, March 14, 1996, 16:20 pm

George T. LaRocca
Product Manager, Insecticide/Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
Washington, D.C. 20460

Re: Damminix. EPA Reg. # 56783-1

Dear Mr. LaRocca,

Thank you very much for being available this afternoon by telephone. By now you will have received the fax that I sent you earlier today. I am happy to make the changes you suggested. We are getting a final count in the warehouse now, but I estimate the total number of old boxes to be between 400 and 500, of which 370 will ship to Fire Island Pines. We will now do two things to each of the old boxes that we ship:

(1) We will put a piece of opaque tape over the front and the end labels of each box where it says "for control of Lyme disease carrying ticks", so that at least the word "control" is obscured; and

(2) we will affix to a blank space on the box an additional sticker that reads:

Precautionary statement:

Environmental Hazards: This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

Thank you.

Alexander Kovel

Ecohealth Inc.
33 Mt Vernon Street, Boston, MA 02108,
Telephone: 617 742 2400, Fax 617 742 4953

ViaFax 703 305 6596

Thursday, March 14, 1996

George T. LaRocca
Product Manager, Insecticide Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
Washington, D.C. 20460

Re: Damminix. EPA Reg. # 56783-1

Dear Mr. LaRocca,

I have a question to ask about an understanding you reached with my predecessor at EcoHealth, Fred deFinis, and to ask your permission for a sticker to be applied to the above label on a limited number of boxes.

As I understand the correspondence I have read, EPA, acting through your office, instructed Ecohealth to re-label Damminix in time for the 1996 season. The offending language which we were asked to remove were the words "for control of Lyme disease carrying ticks", since the only claim that had been accepted was "an aid in the control of Lyme disease carrying ticks". In addition, you required us to include certain additional language in the precautionary statement dealing with environmental hazards, as required by PR Notice 93-3. We agreed not to ship product inconsistent with these requirements. Accordingly, we have been making new boxes with new labels that comply.

Although we agreed to destroy the old boxes, I wonder whether in the following instance it would be possible to use the old boxes with a sticker containing the correct language. One of our largest customers is a home owner's association, Fire Island Pines, Fire Island, New York. All of the product they use is applied by a licensed applicator, and they have been using the product for 7 or 8 years now. They treat the entire village with @ 9,000 tubes (and incidentally have had remarkable results). Everyone in the village is well aware of the product and its use. It is an island not easily accessible to any other user. I think you know enough about the circumstances and size of this company to understand that it would be very helpful for us to use some of the old boxes. Under the circumstances, we propose that we make the following sticker label (7.5 x 1.5 inches) and apply it to every box, and if you require, to every tube as well. We would be willing to limit this exemption to this one customer if you so required. Would the following language be agreeable to you?

"In order to comply with EPA labelling requirements, please consider the label changed as follows: (1) the words 'for control of Lyme disease carrying ticks' should be stricken wherever they appear, and replaced with the words "as an aid in the control of Lyme disease carrying ticks"; and (2) The precautionary statement 'Environmental Hazards' should read as follows: 'This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.'

When I called your office to find out your fax number I was told that you would be out of the office tomorrow. With your permission, I will therefore call you this afternoon to follow up on this. I am sorry for the rush, but it would be a very great help to a small company to get an early decision on this matter, since the Pines Association needs to put this product out in early April.. Thank you.

Alexander Kovel

Ecohealth Inc.
33 Mt Vernon Street, Boston, MA 02108,
Telephone: 617 742 2400, Fax 617 742 4953

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 29 1994

300/5472473
17/8

Mr. Fred DeFinis
Ecohealth, Inc.
110 Broad Street
Boston, MA 02110

Dear Mr. DeFinis:

Subject: Labeling on Existing Stocks and Updated Labeling
Damminix
EPA Registration No. 56783-1
Your Letter Dated August 18, 1994

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable, provided that you make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

1. Revise Environmental Hazards as follows:

"This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by disposal of wastes or equipment washwaters."

The statement (by itself) "Do not apply directly to water" is appropriate for products that are residential use only.

2. Your product contains only one active ingredient. Make the term Active Ingredients singular. (Refer to PR Notice 93-8).

Labeling for the Damminix tube is acceptable.

With respect to your request to use existing labeling until August 31, 1995 we agree to allow the conditional marketing of Damminix in its current package and labeling submitted September 1, 1992 through August 31, 1995. It is understood that after September 1, 1995 all product packaged and shipped will carry the labeling submitted with the subject letter plus above comments.

CONCURRENCES

SYMBOL							
SURNAME	<i>Helant</i>						
DATE	<i>8-30-94</i>						

DAMMINIX TUBE LABEL (PROPOSED)

Damminix

ACTIVE INGREDIENTS:

+* Permethrin 7.4%

INERT INGREDIENTS:

..... 92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) *cis/trans* 3-(2,2 dichloroethyl)2,
2-dimethylcyclopropanecarboxylate.

* *Cis/trans* ratio: Min. 35% (+/-) *cis* and max. 65% (+/-) *trans*.

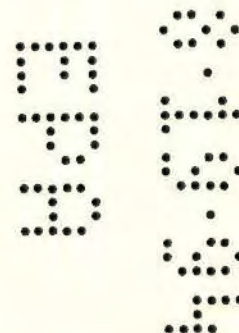
CAUTION: KEEP OUT OF REACH OF CHILDREN

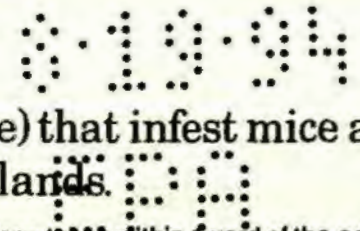
See outer carton for complete directions and precautions

Net contents: 4.5 grams.

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA1





DAMMINIX

A TICK TOXICANT As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA1

ACTIVE INGREDIENTS:

+* Permethrin 7.4%

INERT INGREDIENTS:

..... 92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2 dichloroethenyl)2, 2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

CAUTION: KEEP OUT OF REACH OF CHILDREN

Statement of Practical Treatment

IF SWALLOWED—Contact a physician or Poison Control Center immediately.

IF ON SKIN—Remove contaminated clothing and wash affected areas with soap and water.

IF IN EYES—Flush with plenty of water. Call a physician if irritation persists.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed.

STORAGE AND DISPOSAL:

Store at room temperature. Do not contaminate water, food or feed by storage and disposal.

Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water. Do not contaminate water by disposal of wastes or cleaning of equipment.

ACCEPTED
with COMMENTS
in EPA Letter Dated

ICCO HEALTH, INC.

AUG 29 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

56783-1

CONTENTS:
24 DAMMINIX TUBES
each containing 4.5 grams

300-3H

ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . for control of Lyme Disease carrying ticks.

300/472473

August 18, 1994

Mr. George T. LaRocca
Product Manager
U. S. EPA
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear George,

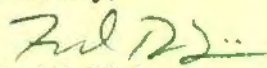
To follow up our phone conversation on correcting our labels, EcoHealthb proposes the following actions:

- 1) We propose to use existing labeled components in our warehouse until August 31, 1995. After that date, the remainder (valued at \$35, 000) will be destroyed.
- 2) All product shipped after September 1, 1995 will bear the proposed labeling attached. (please see both carton and tube label)
- 3) We have discovered that the unit of sale listed on the original registration is "one tube". We would like to update our files to represent the manner in which the product is sold--6, 12, 24, and 96 tube boxes. I have enclosed an amendment reflecting this change.

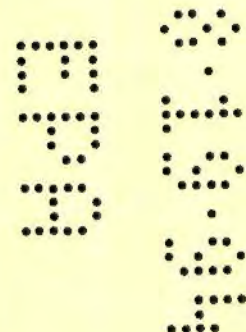
If you approve of these proposed changes, please contact me so that I can relay approval to the regional EPA office in Boston.

Thank you.

Sincerely,


Fred DeFinis

John
8/22/94
With respect to comment 1
I agreed to allow them use
of existing stock with old
label. See previous letter in
file for guidance in
write up
② Check proposed label and if
they make changes as requested
accept.
Do ASAP and call me
to me GL





United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Application for Pesticide: ☐ Registration ☒ Amendment

OPP Identifier Number

138537

Section I

1. Company/Product Number 56783-1	2. Date 8-18-94	3. Product Manager LaRocca	4. Proposed Classification <input checked="" type="checkbox"/> General <input type="checkbox"/> Restricted
--------------------------------------	--------------------	-------------------------------	---

5. Name and Address of Applicant (Include ZIP Code)

EcoHealth, Inc
110 Broad Street
Boston, Ma 02110

☐ Check if this is a new address

6. Product Name

DAMMINIX

Section II - Amendment Information

1. Subject

☐ Resubmission in response to Agency letter ☐ Final printed label in response to Agency letter ☒ Other (explain below)

Date of Letter

Change to reflect package sizes currently in use

Section III

1. Material This Product Will Be Packaged In		2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," Unit package wgt No. per container 4.5 gm 6, 12, 24, 96	Water-Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," Package weight No. per container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper Other (Specify)
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 6, 12, 24, 96 tube boxes	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On material accompanying product		6. Manner in Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other (Specify) <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

Name

Fred DeFinis

Title
PresidentTelephone No. (Include Area Code)
617 742-2400

6. Date Application Received (Stamped)

Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine of imprisonment or both under applicable law.

2. Signature

3. Title

4. Typed Name

Fred DeFinis

5. Date Signed

8-18-94

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in three copies. In order to facilitate review, each type of data submitted must be bound separately, and clearly identified on the front cover including the date submitted.

A copy of the application form and a copy of the label should be bound in each separate volume of the data.

All Data For Which Claims of Confidentiality Are Asserted Must Be Submitted, Bound Separately and Clearly Marked As Such

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to which registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant not residing in the United States must have an authorized agent residing in the United States to act for

them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

301 44/900
38

Mr. Fred DeFinis
President
EcoHealth, Inc.
110 Broad Street
Boston, MA 02110

14 JUN 1993

Dear Mr. DeFinis,

Subject: Resubmission - Compliance with PR Notice 93-3 Labeling
Requirements
Damminix
EPA Registration Number 56783-1
Your Letter Dated June 1, 1993

With respect to your commitment to comply with the labeling requirements of PR Notice 93-3 as outlined in your letter of June 1, 1993, we agree to allow the continued marketing of Damminix in its current packaging in regard to the environmental hazard label statement through August 31, 1995. It is understood that after September 1, 1995 all product packaged and shipped will carry the new label statement regarding the prohibition of application to water and wetlands as well as any other required changes.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

cc: Michael Wood, Director
Compliance Division

CONCURRENCES

SYMBOL								
SURNAME	THM							
DATE	6/2/93							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 11 1993

MEMORANDUM

SUBJECT: Time Extension for Compliance with PR-Notice 93-3 for Damminix (EPA Registration No. 56783-1)

FROM: Lawrence Culleen, Acting Director
Registration Division

TO: Michael Wood, Director
Compliance Division

Ecohealth, Inc. has requested an extension to the April 21, 1994 deadline for compliance with labeling requirements in PR-Notice 93-3 regarding prohibition of application to water and wetlands for their pesticide "Damminix" (EPA Reg. No. 56783-1).

The pesticide is actually a cardboard tube filled with permethrin impregnated cotton. The cotton is foraged by mice and used as nesting material. The tubes are placed around the periphery of yards, parks, woodlands, etc. as an aid in the control of disease carrying ticks that infest mice and nests of mice and subsequently infect animals and humans (Lyme disease).

The registrant has requested an extension to the deadline for labeling changes required by PR-Notice 93-3 in order to exhaust their current label inventory. They estimate that this will be accomplished by August 31, 1995. Based on the limited use pattern and formulation of Damminix, we do not anticipate significant exposure of the pesticide to water or wetlands. Thus, we intend to grant the time extension requested; it is understood that after September 1, 1995 all product packaged and shipped by the registrant of Damminix will carry the new label statement prohibiting application to water.

If you have any questions concerning this memo, please contact George LaRocca of my staff at (703) 305-6100.

Enclosures

cc: Jeff Kempter, RD
Ingrid Sunzenauer, EFED/EEB

CONCURRENCES

SYMBOL	H7505C	H7505C	H7505C					
SURNAME	T.M. Culleen	G. LaRocca	L. Kemp					
DATE	6/9/93	6/9/93	6/9/93					

ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . for control of Lyme Disease carrying ticks.

VIA FAX

June 1, 1993

George T. LaRocca
Product Manager
Insecticide Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
Washington, D.C. 20460

Dear George:

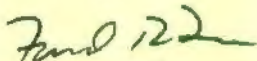
Thank you for your letter of May 17, 1993, regarding P.R. notice 93-3. Our plan for implementing this change is as follows:

1. EcoHealth will continue to sell Damminix in its current packaging through August 31, 1995. This will exhaust most but not all of our packaging inventory.
2. Any remaining old packaging/components will be destroyed to avoid possible confusion.
3. New packaging will be developed which addresses PR notice 93-3 as well as any other label improvements which may be required prior to August, 1995.
4. After September 1, 1995, all product shipped will carry the new wording regarding application to water and wetlands as well as any other required changes.

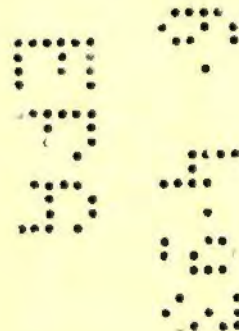
This plan will allow us to continue operations while making the desired changes. In addition, we will emphasize avoiding wetlands in our annual professional training seminars which cover most of the significant professional organizations using Damminix.

Please contact me as quickly as possible regarding your approval, as this will have a major impact on whether/how we can continue operations.

Sincerely,



Fred DeFinis
President



EcoHealth, Inc.

110 Broad Street
Boston, MA 02110

tel/617/742-2400
fax/617/350-6260

Fax Cover Letter

Date:	June 1, 1993
Time:	9:40 am

To/Company:	US EPA - Insecticide Reg. Div	To/Fax#	703 315 596
Attention:	Mr. George T. LaRocca		
From:	Fred DeFina		

Including this cover sheet, there are 2 pages in this transmission.

Attached Documents:

56783-1

Comments:

These are transmitted as checked:

<input type="checkbox"/> As requested	<input type="checkbox"/> For your use	<input checked="" type="checkbox"/> For review and comment	<input type="checkbox"/> No reply necessary
---------------------------------------	---------------------------------------	--	---

Our Fax # is 617/350-6260

If you have any problems or questions,
please call 617/742-2400

ECOHEALTH, INC.

The Makers of **DAMMINIX**

for control of Lyme Disease carrying ticks.

VIA FAX

June 1, 1993

George T. LaRocca
Product Manager
Insecticide Rodenticide Branch
Registration Division (117505C)
U.S. Environmental Protection Agency
Washington, D.C. 20460

Dear George:

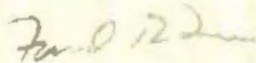
Thank you for your letter of May 17, 1993, regarding P.R. notice 93-3. Our plan for implementing this change is as follows:

1. Ecohealth will continue to sell Damminix in its current packaging through August 31, 1995. This will exhaust most but not all of our packaging inventory.
2. Any remaining old packaging/components will be destroyed to avoid possible confusion.
3. New packaging will be developed which addresses PR notice 93-3 as well as any other label improvements which may be required prior to August, 1995.
4. After September 1, 1995, all product shipped will carry the new wording regarding application to water and wetlands as well as any other required changes.

This plan will allow us to continue operations while making the desired changes. In addition, we will emphasize avoiding wetlands in our annual professional training seminars which cover most of the significant professional organizations using Damminix.

Please contact me as quickly as possible regarding your approval, as this will have a major impact on whether/how we can continue operations.

Sincerely,



Fred DeFinis
President

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 17 1993

300-5440858
38/7

Mr. Fred DeFinis
President
EcoHealth, Inc.
110 Broad Street
Boston, MA 02110

Dear Mr. DeFinis,

Subject: Compliance with Labeling Requirements in PR notice 93-3
Your Letter Dated April 26, 1993

The above referenced letter to Lawrence Culleen was forwarded to me for response. In your letter you indicate that you intend to comply with the labeling changes outlined in PR notice 93-3 concerning the statement prohibiting application to water but request an extension from the April 21, 1994 deadline. In order for us to consider such a request, you must indicate an estimated amount of time needed to comply and/or an agenda for implementing the required changes.

Please feel free to contact me at (703) 305-6100 if you have any questions.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

CONCURRENCES

SYMBOL							
SURNAME	TML						
DATE	5/14/93						

5/7

IRB - please respond directly as appropriate.

ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . for control of Lyme Disease carrying ticks.

George -
Please
respond
Susan

April 26, 1993

Mr. Lawrence E. Cullen
Acting Director
Registration Division (H 7505 C)
Environmental Protection Agency
Washington, D.C. 20460

Dear Mr. Cullen:

We have received PR notice 93-3 "Labeling Statement Prohibiting Application to Water" and intend to comply as quickly as possible but request an extension from the proposed April 21, 1994 deadline. As I explained to Jeff Kempter, EcoHealth is a small company (less than \$1 million in sales). In order to buy packaging and other labeled components at affordable prices, we purchase several year's supply at a time. Even then, the unit cost of our labeling (box and tubes) is over \$3.00 compared to 3-5¢ for a typical pesticide label. The financial cost of complying with the proposed 1994 deadline would be disastrous for our company, and for the thousands of people who depend on Damminix for protection from Lyme disease carrying ticks.

Damminix has much less toxicity and impact on the environment than other tick control methods. In addition, the active ingredient (permethrin @ <1/2 ounce A.I./acre) is impregnated in the cotton fiber and nearly insoluble in water.

If Damminix is no longer available, homeowners will be forced to resort to compounds that are used at significantly higher rates and have much more environmental impact. If you can give EcoHealth some flexibility on the deadline, we will make the desired changes as quickly as we are able while continuing to provide homeowners with the least toxic approach to deer tick control. Please contact me regarding an extension to the deadline. Thank you for your consideration.

Sincerely,

Fred DeFinis

Fred DeFinis
President

CERTIFIED MAIL #655 440 088
RETURN RECEIPT REQUESTED

RECEIVED
5/4/93
REGISTRATION DIVISION
H-7505C
RD-7790

[5] From: DCOPP2-POADMIN 3/22/93 8:21AM (12152 bytes: 154 ln, 1 fl)
Subject: PR Notice 93-3 (3-8-93)

----- Message Contents -----

Text item 1:

March 9, 1993

PESTICIDE REGULATION (PR) NOTICE 93-3

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS
AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Registration of Pesticides

SUBJECT: Labeling Statement Prohibiting Application to Water

This notice explains EPA's policy concerning the labeling statement which prohibits application of a pesticide to water and specifies a revised statement. Until the new statement is adopted on pesticide product labels, the enforcement interpretation in this notice applies to the existing labeling statement. This notice pertains only to the labeling statement on pesticide products and does not address the term "wetlands" as defined by EPA with respect to the Clean Water Act.

I. BACKGROUND

Two issues have arisen regarding the labeling statement which prohibits direct application of a pesticide to water: (1) what does the term "wetlands" in this statement mean and (2) to which uses does the "Do not apply directly to water" prohibition apply?

A. Meaning of "Wetlands"

In 1984, EPA changed the "Do not apply directly to water" statement on pesticides with outdoor, terrestrial uses to include the term "wetlands." The revised statement read: "Do not apply directly to water or wetlands (swamps, bogs, marshes, potholes)." The purpose of the change was to extend protection to areas where aquatic life might be affected by pesticides. The statement was intended to be consistent with the meaning of wetlands as defined in a 1980 Federal Register notice pursuant to the Clean Water Act (CWA), Section 404, as follows:

"The term 'wetlands' means those areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs and similar areas." [40 CFR 230.3(t)]

The Federal Manual for Identifying and Delineating Jurisdictional Wetlands, jointly issued by EPA, the Army Corps of Engineers, the Soil Conservation Service and the U.S. Fish and Wildlife Service in 1989, was written to implement the regulatory definition of wetlands and included criteria regarding vegetation types, soil types and wetland hydrology. Subsequently, EPA received inquiries from the U.S. Department of Agriculture, state regulatory officials, the National

Forest Products Association and other groups as to whether the term "wetlands" on pesticide labels has the same meaning as for Clean Water Act jurisdiction. As of January 4, 1993, EPA has joined the U.S. Army Corps of Engineers in using the 1987 Corps of Engineers Wetlands Delineation Manual. This action does not have an impact on this PR Notice.

On April 16, 1991, EPA issued a memorandum to the EPA Regions clarifying the meaning of the term "wetlands" on pesticide labels (Attachment 1). The key message was that pesticides bearing a "wetlands" warning must not be applied directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. For enforcement purposes, the presence of residues from pesticides bearing a "wetlands" label warning for these areas could indicate a "use inconsistent with the labeling" (i.e., misuse).

To avoid confusion over the meaning of the term "wetlands" on pesticide labels versus the meaning of "wetlands" in connection with the Clean Water Act, EPA is revising the current water prohibition statement by deleting this term. The enforcement interpretation in the previous paragraph will remain in effect until the term "wetlands" no longer appears on pesticide labeling.

B. Use Patterns to Which the Water Prohibition Applies

A conflict occurs when the "Do not apply directly to water" statement is present on the labeling of products which are registered for both terrestrial and aquatic uses. While EPA does not intend for this statement to apply to the aquatic uses, the uses to which it applies are not clear. For example, a product which is registered as an insecticide against adult mosquitoes may have both aquatic and terrestrial sites in the use directions. Because the current "Do not apply directly to water" statement is unqualified, it applies to all of the registered sites. To correct this conflict, EPA is revising the water prohibition statement to clarify that it applies only to terrestrial uses.

II. POLICY

In the Environmental Hazards section of pesticide labeling, the statement "Do not apply directly to water or wetlands (swamps, bogs, marshes or potholes)..." should be replaced with:

"For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark."

This statement will correct the two problems discussed above. First, inserting the phrase "For terrestrial uses" at the beginning of the water prohibition statement indicates that it applies to terrestrial, forestry (except aerial application) and domestic outdoor uses only [refer to Appendix A of 40 CFR Part 158 for descriptions of these general use patterns]. The revised statement does not apply to other general use patterns--aquatic (e.g., mosquito larvicides or adulticides, aquatic herbicides, piscicides, slimicides, etc.), greenhouse and indoor uses.

Second, the new statement more clearly describes where pesticides intended for terrestrial use may not be applied. In that statement, the term "water" means natural or man-made bodies of water such as

lakes, streams, rivers, canals, ponds, reservoirs, bays, oceans, etc. "Areas where surface water is present" means such areas as swamps, bogs, potholes and marshes where water is present on the soil surface; this phrase does not include irrigation ditches which have been drained. "Intertidal areas below the mean high water mark" means coastal and estuarine areas which are exposed during low tide, but covered during high tide.

III. EFFECTIVE DATE AND REQUIRED ACTIONS

This policy is effective immediately. The Agency intends to accept applications for registration of new products with terrestrial, forestry (except aerial application) and domestic, outdoor uses only if they comply by inserting the label statement shown in Section II.

Registrants of currently registered products with these same uses should also adopt the label statement shown in Section II. If the exact wording shown in Section II is used, registrants of existing products may accomplish this change by notification to EPA (see 40 CFR 152.46 or PR Notice 88-6). Alternate wording to the above label statement may only be adopted by submitting an application for amendment to the appropriate EPA Product Manager and obtaining EPA approval. To promote uniformity of this particular label statement across all affected products, EPA does not encourage registrants to seek alternate wording.

Label changes should be made by registrants and distributors no later than April 21, 1994. Persons other than registrants or distributors should not distribute or sell products after April 21, 1996 unless the labeling complies with this notice. The Agency may issue a notice of intent to cancel or take enforcement action against any product that is distributed or sold by a registrant (or distributor) after this date unless its labeling complies with this notice. If you have questions regarding this policy, you may contact Jeff Kempter, Registration Division (703-305-5448).

/signed/

Douglas D. Campt, Director
Office of Pesticide Programs

File item 2: PR93-3.ATT 3/22/93 8:16AM

File
ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . for control of Lyme Disease carrying ticks.

56783-1

4-13-3-1

November 12, 1992

Mr. George LaRocca
Product Manager
Office of Pesticide Programs
Environmental Protection Agency
401 M Street S.W. Room 202
Washington, D.C. 20460

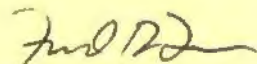
Dear George:

Thank you for your advice on labeling. We will exhaust our current supply of printed labeling, then incorporate the suggested changes in the next printing.

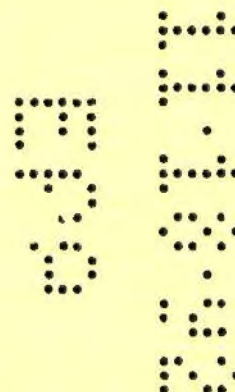
As there seems to have been much confusion regarding primary and secondary labels over the years, we would like you to review proposed changes before we print new labels.

Thank you for your help in this matter.

Sincerely,



Fred DeFinis
President



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 29 1992

300/5425822
18

Mr. Fred DeFinis
President
EcoHealth, Inc.
110 Broad Street
Boston, MA 02110

Dear Mr. DeFinis,

Subject: Current Labeling
Damminix
EPA Registration Number 56783-1
Your Submission Dated September 1, 1992

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the reasons given below:

There appears to be some confusion over label requirements for unit packaging as is the case with the subject product. Currently the tube label contains some but not all of the label text appearing on the carton label. If it is your intention to reproduce the carton label text onto the tube label, you must reproduce the complete text. As such the following statements as stated in our letter of June 26, 1992 must be added to the label:

- It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
- Precautionary Statements
- Hazards to Humans and Domestic Animals
- Environmental Hazards
- Statement of Practical Treatment
- In addition, in our letter of February 28, 1989 it is stated that the efficacy data on file do not support the claim "for control of" [Lyme disease carrying] ticks instead of "as an aid in the control of." Delete "for control of" from the label.

Alternatively, you may retain the label text appearing on the outer carton label and include only the following label statements on the unit or tube label:

CONCURRENCES							
SYMBOL							
SURNAME	JML						
DATE	10/27/92						

1. Product Name
2. Ingredient Statement
3. Appropriate Signal Word
4. Child Hazard Warning
5. EPA Registration Number
6. Reference statement to the label of the outer package for directions and precautions.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

ECOHEALTH, INC.

The Makers of **DAMMINIX** . . . *for control of Lyme Disease carrying ticks.*

September 1, 1992

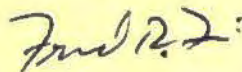
Mr. George T. LaRocca
Product Manager
Insecticide - Rodenticide Branch
Registration Division
United States Environmental Protection Agency
Washington, D.C. 20460

Dear George:

We received your letter dated June 26, 1992 referring to our Damminix label (EPA 56783-1) As we discussed, the suggested changes were made some years ago, but perhaps you were looking at an old label.

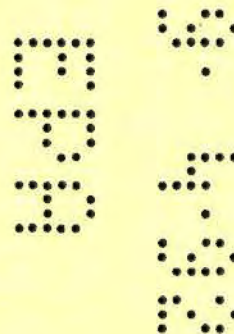
Five copies of the corrected labeling which has been in use for at least 4 years are enclosed for your files.

Sincerely,



Fred DeFinis

/enc.



CARTON LABEL

A TICK TOXICANT As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA1

ACTIVE INGREDIENTS:

+* Permethrin 7.4%

INERT INGREDIENTS:

..... 92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2 dichloroethenyl)2,
2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

CAUTION: KEEP OUT OF REACH OF CHILDREN

Statement of Practical Treatment

IF SWALLOWED—Contact a physician or Poison Control Center immediately.

IF ON SKIN—Remove contaminated clothing and wash affected areas with soap and water.

IF IN EYES—Flush with plenty of water. Call a physician if irritation persists.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs and horses.

To apply, open both ends of tube. For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed.

STORAGE AND DISPOSAL:

Store at room temperature. Do not contaminate water, food or feed by storage and disposal.

Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water. Do not contaminate water by disposal of wastes or cleaning of equipment.

EcoHEALTH, INC.

CONTENTS:
24 DAMMINIX TUBES
each containing 4.5 grams

DIRECTIONS FOR USE:

FOR OUTDOOR APPLICATION ONLY. To apply, place tubes flat on the ground in all areas to be treated. Place product in grid design with not more than 10 yards between each tube in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Replace tube when nesting material is completely removed.

STORAGE AND DISPOSAL:

Store at room temperature. Do not contaminate water, food or feed by storage and disposal. This product is biodegradable and may be left in the application site or may be collected and put in trash.

DAMMINIX

for Control of Lyme Disease Carrying Ticks

A TICK TOXICANT. As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

ACTIVE INGREDIENTS: +*Permethrin; 7.4% **INERT INGREDIENTS:** 92.6%, Total: 100.0%

+(3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethenyl) 2,2-dimethylcyclopropanecarboxylate. *Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

ECOHEALTH, INC. 1989 33 Mount Vernon Street Boston, MA 02108

EPA Reg. No. 56783-1 EPA Est. No. 5693 MA1 U.S. Patent No. 4,662,104 **Contents: 4.5 grams**

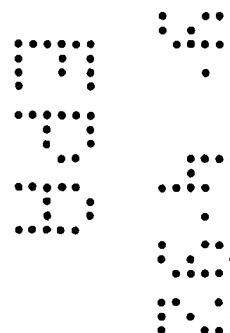
CAUTION: DO NOT ALLOW CHILDREN OR PETS TO HANDLE OR PLAY WITH THIS PRODUCT

IF SWALLOWED: Contact a physician or Poison Control Center.

IF ON SKIN: Wash affected areas with soap and water.

IF IN EYES: Flush with plenty of water.

TUBE LABEL



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

26 JUN 1992

Mr. Fred DeFinis
President
EcoHealth, Inc.
110 Broad Street
Boston, MA 02110

Dear Mr. DeFinis,

Subject: Damminix
Follow-Up Review of Label
EPA Registration Number 56783-1

In connection with a sample label review of the above product that had been packaged, labeled and released for shipment, it appears that the retail size product label was deficient as follows:

- It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
- Precautionary Statements
- Hazards to Humans and Domestic Animals
- Environmental Hazards
- Statement of Practical Treatment
- In addition, in our letter of February 28, 1989 it is stated that the efficacy data on file do not support the claim "for control of" [Lyme disease carrying] ticks instead of "as an aid in the control of."

The sample label collected appears to be the tube label which was identified in the original application form of October 20, 1986 as the retail container size. Please refer to the last stamped labeling dated July 29, 1988 for further details concerning acceptable labeling for this product and submit five copies of corrected finished labeling.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

CONCURRENT REGISTRATION							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 18 1992

455/5419838
38/5MEMORANDUM

SUBJECT: ENFORCEMENT CASE REVIEW REQUEST
 OCM/ECR LOG NO. 92-I-05
 INSPECTION NO. PJR-9205
 Registrant - Ecohealth, Inc.
 EPA Reg. No. 56783-1 (Damminix)

FROM: George LaRocca, Product Manager 13
 Insecticide-Rodenticide Branch
 Registration Division (H7505C)

TO: Mary McDonnell, HQ Regional Coordinator
 Case Support Branch
 Compliance Division (EN-342)

In regard to the specific comments made in the enforcement case review memo of 3/12/92, it appears that the sample label reviewed is indeed missing the following statements:

- It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
- Precautionary Statements
- Hazards to Humans and Domestic Animals
- Environmental Hazards
- Statement of Practical Treatment

The sample label collected appears to be the tube label of a two package product, outer container label and inner tube label. The tube seems to be missing some of the required text that appears on the container label; however, this requirement was not made clear to the registrant in our June 22, 1987 Notice of Registration. We are presently notifying the registrant that the product must bear a complete label on both the unit package and outer container.

The statements of practical treatment and the disposal statement are slightly different from the last accepted label but are nonetheless acceptable.

The statement "Keep out of Reach of Children" is required to appear on the container label; the individual tube label (which is apparently the sample submitted) must carry the statement "Do not allow children or pets to handle or play with this product."

CONCURRENCES

SYMBOL	OC: Herb Harrison, Chief					
SURNAME	Insecticide-Rodenticide Branch					
DATE	6/17/92					

1 Team B 7156783-1
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

Date: 3/17/92

TRANSMITTAL SHEET:

SUBJECT: Enforcement Case Review Request

OCM/ECR LOG NUMBER: 92-I-05

INSPECTION NUMBER: PJR 9205 2-5-92

FROM: Case Support Branch, Compliance Division, OCM-OPTS

TO:

☐

Disinfectant Branch

☐

Herbicide - Fungicide Branch

☒

~~Insecticide - Rodenticide Branch~~

☐

Registration Support & Emergency Response

The attached inspection file requires technical evaluation of the following Product element/s:

☐

Registration

☐

Content

☐

Formulation

☐

(Device ?)

☐

Efficacy

☐

Toxicity

☒

Labeling

☐

Claims

☐

Advertising

☐

Packaging

☐

Other

Mary McDonald
Case Officer

This review is requested because:

See next page.

U.S. ENVIRONMENTAL PROTECTION AGENCY COLLECTION REPORT				1. TYPE SAMPLE P.E.I.	2. SAMPLE NO. "PJR 9205 2-5-92"
3. DATE COLLECT 2-5-92	4. PROJ CODE --	5. REGION NO. I	6. INSP NO. 2018	7. REGISTRATION NO. 56783-1	8. ESTABLISHMENT NO. 5693-MA-1
9. DATE(S) SHIPPED n/a				10. FLAG Region I request	
11. PRODUCT IDENTIFICATION (Name, Brand, Q.C. Statement, Active Ingredients, Firm Name and Address, etc.) Cardboard Tube "DAMINIX***ACTIVE INGREDIFNTS: *Permethrin: 7.4%*** EUCHEALTH, INC. 33 Mount Vernon Street, Boston, MA 02108***Contents: 4.5 grams***"					
12a. PRODUCER ESTABLISHMENT SHIELD PACKAGING COMPANY, INC.					
b. STREET ADDRESS P.O.Box729 Peter St.			c. CITY Webster	d. STATE MA	e. ZIP CODE 01570
13a. SHIPPER same as above					
b. STREET ADDRESS			c. CITY	d. STATE	e. ZIP CODE
14a. DEALER n/a					
b. STREET ADDRESS			c. CITY	d. STATE	e. ZIP CODE
15. RECORDS AND SAMPLE SENT TO (Specify location)					
a. ORIGINAL RECORDS EPA Region I offices			b. PRODUCING REGION COPY Region I	c. SAMPLE	
d. SAMPLE DELIVERED TO: EPA Region I			e. DATE	f. B/L NO. n/a	
16. LOT OR CODE NOS. 12345 1938					
17. AMOUNT BEFORE SAMPLING 4 cases, 20 boxes per case, 12, 4.5 g tubes each					
18. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION 1 4.5 gram tube taken from prevoiusly unopened shipping case, packaged labeled and released for shipment. photo copy of label as Doc. sample					
19. SAMPLE PREPARED IN THE FOLLOWING MANNER Sample(s) identified as "PJR 9205 2-5-92" "PJR" polybagged, and sealed with M.D.F.A. seals, as "PJR 9205 2-5-92", Paul J. Ricco."					
20. RELATED SAMPLES COLLECTED FROM SAME SHIPMENT OR AT THE SAME PRODUCER ESTABLISHMENT "PJR 9205/9224 2-5-92"					
21. REASON FOR COLLECTION Region I request					
22. NOTICE OF INSPECTION ISSUED			23. RECEIPT FOR SAMPLES ISSUED		
24. REMARKS The labels collected have been compared to the samples that have been packaged, labeled, and released for shipment, and have been found to be identical.					
25. SAMPLE COST \$ n/a	C	V	B	26 COLLECTION STA Boston, MA	27. COLLECTOR'S NAME (Type) AND SIGNATURE Paul J. Ricco, Paul J Ricco
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		79

DIRECTIONS FOR USE:

FOR OUTDOOR APPLICATION ONLY: To apply, place tubes flat on the ground in all areas to be treated. Place product in grid design with not more than 10 yards between each tube in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Replace tube when nesting material is completely removed.

STORAGE AND DISPOSAL:

Store at room temperature. Do not contaminate water, food or feed by storage and disposal. This product is biodegradable and may be left in the application site or may be collected and put in trash.

DAVINIX

for Control of Lyme Disease Carrying Ticks

Doc. Sample DFR 4205 2-5942 R/R

A TICK TOXICANT. As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

ACTIVE INGREDIENTS: + Permethrin: 7.4% **INERT INGREDIENTS:** 92.6%, Total: 100.0%
+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethyl) 2,2-dimethylcyclopropane-1-carboxylate. * Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.
ECOHEALTH, INC. © 1989 33 Mount Vernon Street Boston, MA 02108
EPA Reg. No. 56783-1 EPA Est. No. 5693 MA1 U.S. Patent No. 4,460,204 **Contents: 4.5 grams**

CAUTION: DO NOT ALLOW CHILDREN OR PETS TO HANDLE OR PLAY WITH THIS PRODUCT.

IF SWALLOWED: Contact a physician or Poison Control Center.
IF ON SKIN: Wash affected areas with soap and water.
IF IN EYES: Flush with plenty of water.



U. S. ENVIRONMENTAL PROTECTION AGENCY

NOTICE OF INSPECTION

ADDRESS (EPA Regional Office)

Pesticide Bureau
100 Cambridge Street
Boston, MA 02202

DATE

2-5-92

HOUR

9:00

A.M.
P.M.

NAME OF INDIVIDUAL

Robert L. McCullum

TITLE

Technical Director

FIRM NAME

Shield Packaging Company
Inc

FIRM ADDRESS (Number, Street, City, State and Zip Code)

Peter Street
P.O. Box 729
Webster, MA 01570
508-949-0900

SIGNATURE OF EPA EMPLOYEE

Paul G. New

TITLE

Sup Inspector

REASON FOR INSPECTION

☒ FOR THE PURPOSE OF INSPECTING AND OBTAINING SAMPLES OF ANY PESTICIDES OR DEVICES PACKAGED, LABELED, AND RELEASED FOR SHIPMENT, AND SAMPLES OF ANY CONTAINERS OR LABELING FOR SUCH PESTICIDES OR DEVICES, IN PLACES WHERE PESTICIDES OR DEVICES ARE HELD FOR DISTRIBUTION OR SALE (Sec. 9(a) and 12(a)(2)(B)).☐ FOR THE PURPOSE OF INSPECTING AND OBTAINING COPIES OF THOSE RECORDS SPECIFIED IN SECTION 8 AND 40 CFR PART 169. (Sec. 8 and 12(a)(2)(B)).

VIOLATION SUSPECTED:

possible production and distribution
of pesticides which have been cancelled

Section 8, 9(a) and 12(a)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 et seq.) are quoted on the reverse of this form.



RECEIPT FOR SAMPLES

DATE 02/05/92

NAME OF INDIVIDUAL Robert L. McCollum	TITLE Technical Director
FIRM NAME Shield Packaging Company, INC. 508-949-0900	ADDRESS (Street, City, State and Zip Code) Peter Street P.O. Box 774 Webster, MA. 01570

SAMPLE NUMBERS

PSR 9205 / 9214 2-5-92 Rth

SAMPLES COLLECTED (Describe fully, List Registration, Lot, Batch, Model, Serial Numbers and other positive identifications.)

The following samples were collected by the U.S. Environmental Protection Agency and receipt is hereby acknowledged pursuant to Section 9.(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 g). This section is quoted on the reverse of this form.

DAMMINIX 56783-1 2438 & accompanying doc sample (4.5 grams)
Shoo-fly screen & surface insect spray 3546-27a 1179B (14 oz can) accompanying doc sample
SPORT TICK-STOP 16 oz can 3546-28 0142A
BUTCHER'S CLOCKWORK D. disinfectant Deodorizer 7176-12 2027A doc sample
SANITIZER SPRAY NET WT (16 oz can)
OZ IUM NET WT 14.5 oz can & accompanying 3347-9 1270C doc sample

DOC. SAMPLES:

Shoo-fly BLAST 14 oz empty can 3546-27
Shoo-fly Garden Fogger 15 oz Label EPA 5693-46-3546
Shoo-fly MITEY 4 oz empty can EPA 4816-505-3546
Shoo-fly Indoor Fogger 9 oz Label EPA 5693-61-3546
Shoo-fly NEW FLEA Fogger 9 oz Label EPA 5693-61-3546

ACKNOWLEDGMENT OF PRODUCER/REGISTRANT

The undersigned acknowledges that the samples shown above were obtained from pesticides or devices that were packaged, labeled, and released for shipment.

SIGNATURE (Owner, Operator, or Agent) <i>Robert L. McCollum</i>	TITLE (Owner, Operator or Agent) Tech Director	
<input checked="" type="checkbox"/> DUPLICATE SAMPLES REQUESTED AND PROVIDED <input type="checkbox"/> DUPLICATE SAMPLES NOT REQUESTED	SAMPLES WERE <input type="checkbox"/> PURCHASED <input checked="" type="checkbox"/> BORROWED	
AMOUNT PAID FOR SAMPLES \$ WIC <input type="checkbox"/> CASH <input type="checkbox"/> VOUCHER <input type="checkbox"/> TO BE BILLED		
NAME OF COLLECTOR (Print or type) Paul Rios	TITLE OF COLLECTOR Inspector	SIGNATURE OF COLLECTOR <i>Paul Rios</i>

ESTABLISHMENT INSPECTION REPORT				1. VISIT
2. REGION NO. 01/MA		3. INSPECTOR NO. 2018		4. DATE OF VISIT 2-5-92
		5. ESTAB. REGISTRATION NO. 5693-MA-001		
6. ESTABLISHMENT NAME AND ADDRESS (Including Street, city, state, ZIP code, county and phone number) Shield Packaging Company, Inc. Peter Street P.O. Box 729 Webster, MA 01570 (508) 949-0900		7. RELATED FIRMS Shield Packaging Company, Inc. 1565 G Street Chino, CA 91710		
8. TYPE OF ESTABLISHMENT Producer	9. TYPE OF OWNERSHIP Corporation	10a. TOTAL ANNUAL SALES 6 - 7million	10b. PERCENT PESTICIDES 1 - 2%	
11. NAMES AND TITLES OF OF PRINCIPAL OFFICERS, PARTNERS OR OWNERS George Bates , President Lou Scagzie , Executive Vice President Bruce Simpson , Vice President Operations				
12. PERSONS INTERVIEWED (Give name, title, phone number and responsibility) Robert McCollum - Technical Manager Ian Copland - Administrative Manager				
13a. PHYSICAL SAMPLES COLLECTED		13b. DOCUMENTARY SAMPLES		13c. LABELS REVIEWED WITHOUT SAMPLES
EPA REGISTRATION NO.	SAMPLE NO.	EPA REGISTRATION NO.	SAMPLE NO.	EPA REGISTRATION NO.
56783-1	PJR 9205	3546-27	PJR 9210	572-321
3546-27	PJR 9206	5693-46-3546	PJR 9211	8590-598
3546-28	PJR 9207	4816-508-3546	PJR 9212	8590-479
7176-12	PJR 9208	5693-61-3546	PJR 9213	2347-9
2347-9	PJR 9209	5693-61-3546	PJR 9214	2398-7
		5693-76-3546	PJR 9215	2398-7
		5693-46-3546	PJR 9216	
14. REMARKS <u>DOCUMENTARY SAMPLES (Continued)</u> 3546-27 PJR 9217 5693-61 PJR 9223 5693-46 PJR 9218 5693-46 PJR 9224 3546-27 PJR 9219 4186-508 PJR 9220 7176-6 PJR 9221 56783-2 PJR 9222				
15. SIGNATURE OF INSPECTOR			16. INSPECTOR'S STATION Boston, MA <i>Paul J. Miller</i>	

ATTACHED NOTIFICATION

TO: PM _____

FROM: REG. SUPPORT BR.

NO NEW LABEL ✓

EPA REG. NO. 56783-1

NEW LABEL ATTACHED _____

COMPANY NAME EcoHealth Inc

NEW CSF ATTACHED _____

_____ THIS IS AN ADDITIONAL BRAND NAME

_____ THIS IS A CSF PERMITTED UNDER PR NOTICE 88-6

_____ THIS IS A LABEL CHANGE PERMITTED UNDER PR NOTICE 88-6

_____ THIS WAS SENT TO SIG FOR CODING AND/OR MICROFICHING

✓ _____ FILE IN JACKET

ECOHEALTH, INC.

The Makers of **DAMMINIX**

April 14, 1989

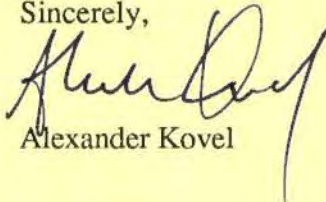
Dr. Alexandre R. Tarsey
Registration Support Branch
Registration Division (H7505C)
United States Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Dr. Tarsey:

This is in response to your letter of February 28, 1989, concerning our pesticide product, Registration No. 56783-1.

In view of that letter, and after further consideration, we have decided to withdraw our notification dated December 7, 1988, and not to pursue the proposed label change. We will not be filing an application for an amendment, but instead will use the label previously approved.

Sincerely,



Alexander Kovel

/enc.

✓ cc: Product Manager 15

A TICK TOXICANT For the control of deer ticks, *Ixodes dammini* (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths and in woodlands.

EPA Reg. No. 56783-1

ACTIVE INGREDIENTS:

+* Permethrin 7.4%

INERT INGREDIENTS:

..... 82.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethenyl)2,2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

AFTER

CAUTION: KEEP TUBES AWAY FROM CHILDREN

Statement of Practical Treatment

IF SWALLOWED—Contact a physician or Poison Control Center immediately.

IF ON SKIN—Remove contaminated clothing and wash affected areas with soap and water.

IF IN EYES—Flush with plenty of water. Call a physician if irritation persists.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs and horses.

To apply, open both ends of tube. For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed.

STORAGE AND DISPOSAL:

Store at room temperature. Do not contaminate water, food or feed by storage and disposal.

Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water. Do not contaminate water by disposal of wastes or cleaning of equipment.

EcoHEALTH, INC. ©1989

33 Mount Vernon Street
Boston, MA 02108
U.S. Patent No. 4,562,104

CONTENTS:

24 DAMMINIX TUBES
each containing 4.5 grams

Open Other End

BEFORE

A TICK TOXICANT

As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA1

ACTIVE INGREDIENTS:

+ * Permethrin 7.4%

INERT INGREDIENTS:

..... 92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) *cis/trans* 3-(2,2 dichloroethenyl)2, 2-dimethylcyclopropanecarboxylate.

* *Cis/trans* ratio: Min. 35% (+/-) *cis* and max. 65% (+/-) *trans*.

CAUTION: DO NOT ALLOW CHILDREN OR PETS TO HANDLE OR PLAY WITH THIS PRODUCT

Statement of Practical Treatment

IF SWALLOWED—Contact a physician or Poison Control Center immediately.

IF ON SKIN—Remove contaminated clothing and wash affected areas with soap and water.

IF IN EYES—Flush with plenty of water. Call a physician if irritation persists.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs and horses.

To apply, open both ends of tube. For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 meters in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 meter of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 meters surrounding the yard area to be protected should be treated. Replace tube when nesting material is completely removed.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 meters between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding woodlot. Placing tubes near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Replace tube when nesting material is completely removed.

STORAGE AND DISPOSAL:

Store at room temperature. Do not contaminate water, food or feed by storage and disposal.

Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water. Do not contaminate water by disposal of wastes or cleaning of equipment.

ECO HEALTH, INC. © 1988

33 Mount Vernon Street
Boston, MA 02108
U.S. Patent No. 4,662,104

CONTENTS:

50 DAMMINX TUBES

each containing 4.5 grams

rin, 7.4%

U.S. Patent No. 4,662,104

EPA Reg. No. 56783-1
EPA Est. No. 5693 MA 1

When to apply Damminix:

Damminix is applied in the spring, after April 1, and in the summer, as late as mid September. **Two applications are recommended each year.** Treatment can begin at either time. Both are important, and the summer application is essential.

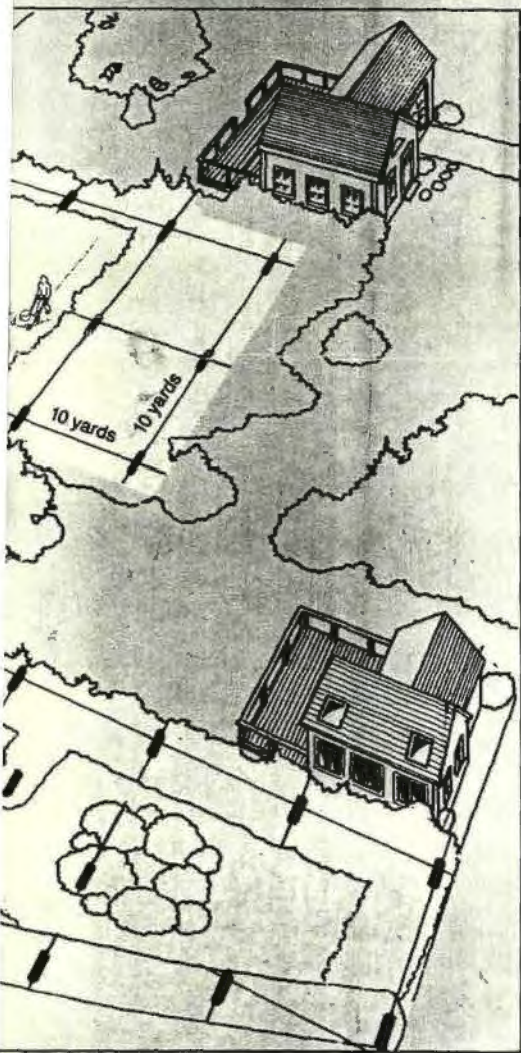
Most cases of Lyme disease are acquired in May, June or July when the nymphal (pinhead size) ticks are feeding.

Damminix works in two ways:

- ✱ **In the spring:** by killing some nymphal ticks.
- ✱ **In the mid to late summer:** by killing the newly hatched larval ticks that will be next year's infected nymphs. Do not omit the summer application.

EcoHEALTH, INC.

33 Mount Vernon Street, Boston, MA 02108

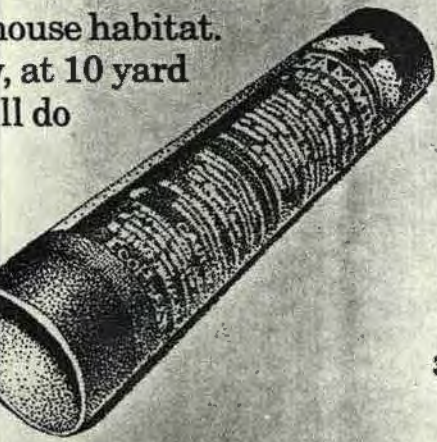


Damminix works, even if neighboring land is not treated.

Each tube of **Damminix** kills the ticks on mice foraging nearby. If all the mouse habitat near your home is properly treated (see diagram), you will protect your home from Lyme disease carrying ticks.

If your yard is properly treated, there is little threat that you will be bitten by a tick migrating from untreated land. Ticks do not travel far on their own. Even if a tick from elsewhere is carried on to your land by a host such as a bird, dog or deer, the risk of its giving you Lyme disease is slight. Usually a tick on an animal would already be feeding on that animal — and ticks feed only once in each stage of their life.

mouse habitat.
at 10 yard
do



EcoHEALTH, INC.

33 Mount Vernon Street, Boston, MA 02108 (617) 742-2400

A TICK TOX
info nice

EPA Reg. No. 56783-1
ACTIVE INGREDIENTS
INERT INGREDIENTS

(3-phenoxyphenyl
2-dimethylcyclopropyl
+ C14/18 trans ratio: 1:1

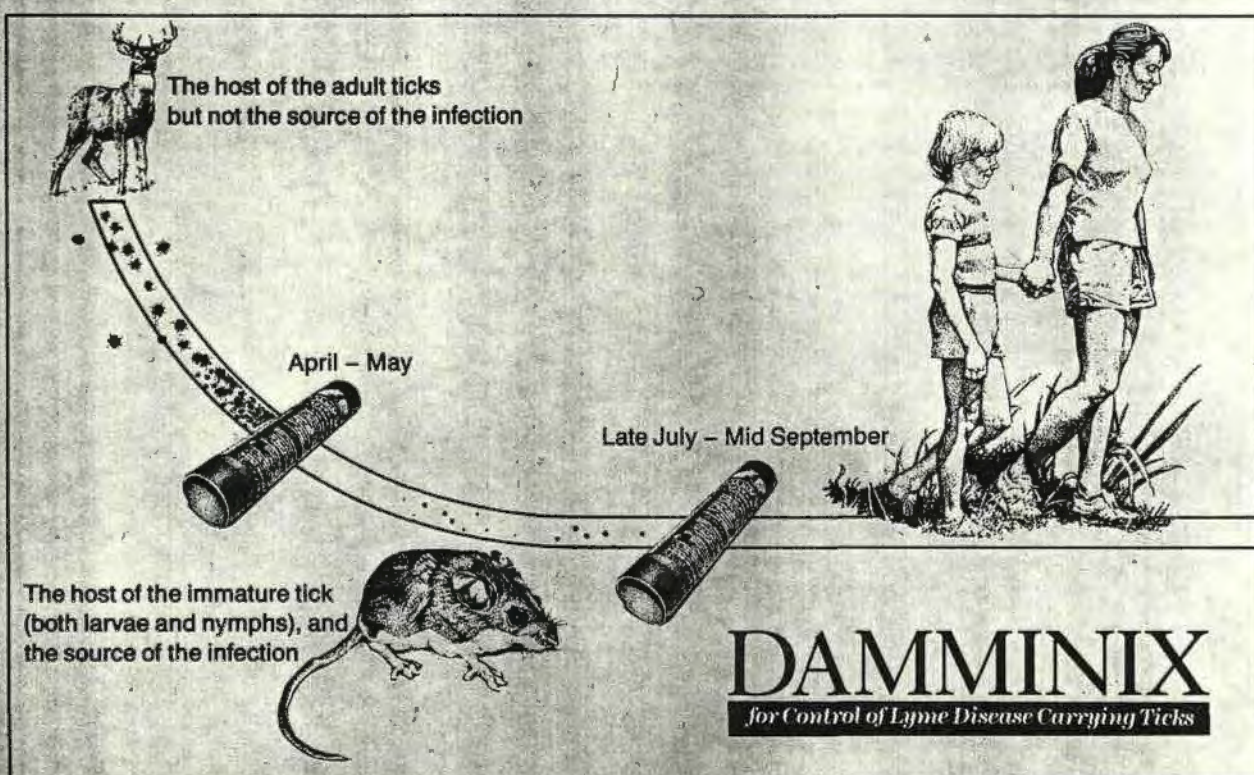
CAUTION
Statement of
IF SWALLOWED
Immediately
IF ON SKIN—
areas with sc
IF IN EYES—
tion persists.

**DIRECTIONS FOR
USE**
It is a violation of
labeling.
**FOR OUTDOOR
USE**
the mice that are
carriers of Lyme
disease to hunt.
To apply, open b
in all brush-ov
between tubes
limited to areas
grasslands. Tut
ends. Product v

24 Tubes

ACTIVE INGREDIENT: Permethrin, 7.4%

U.S. Patent No.



When to apply Damminix

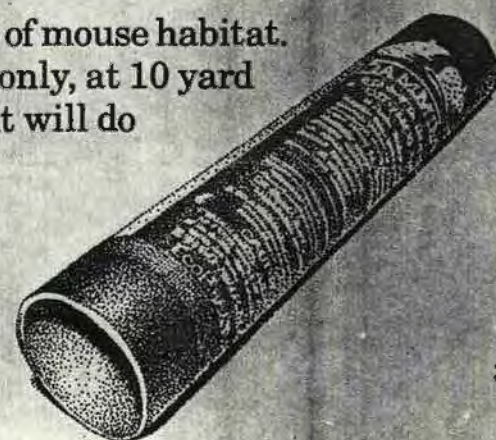
Damminix is applied in the spring, summer, as late as mid September. **recommended each year.** Treatn Both are important, and the summ

Most cases of Lyme disease are acq when the nymphal (pinhead size) ti **Damminix works in two ways:**

- * **In the spring:** by killing sor
- * **In the mid to late summer:** larval ticks that will be next; Do not omit the summer appl

To determine how many tubes of Damminix you need:

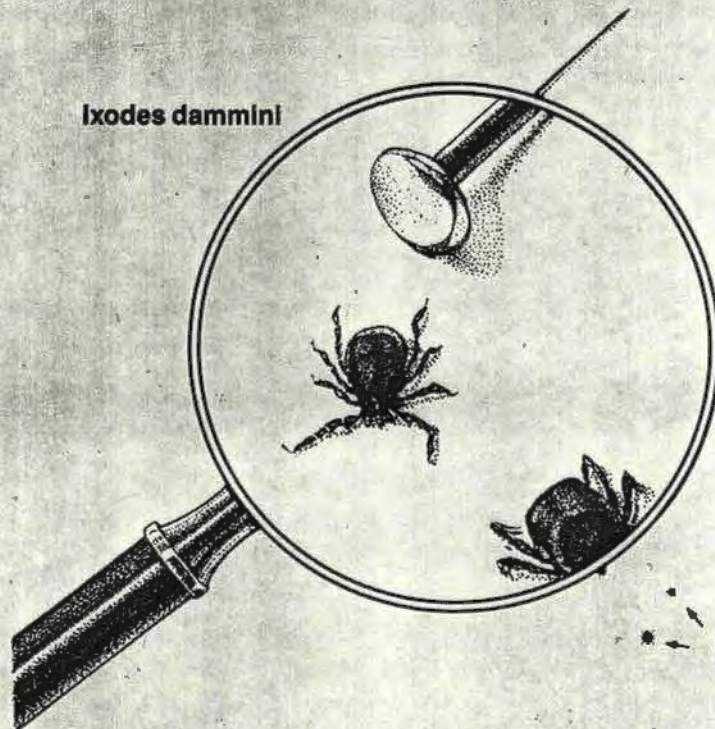
- * You can protect all or any part of your property. If you want to treat only part of it, choose the part you walk through or use most.
- * Once you select the area you want to protect, notice how much of it is covered or bordered by mouse habitat (brush, shrubs, flowerbeds, woodpiles, hedges, rock walls, deep fallen leaves, and similar areas where mice can take cover and which are therefore likely to contain mouse burrows). Mice do not live on your lawn.
- * Treat at the rate of 24 tubes per half-acre (approx. 22,000 sq. ft) of mouse habitat. Tubes are easily placed, flat on the ground, in mouse habitat only, at 10 yard intervals (see diagram). Closer intervals are not necessary but will do no harm. **Every tube helps.**
- * **Damminix** comes in two sizes: a 24-tube and a 12-tube box. Unused tubes can be kept for future applications.



ECO

33 Mount Vern

Ixodes dammini



How Damminix works:

Deer ticks, (*Ixodes dammini*), become a stage of the tick is particularly dangerous active in the spring and early summer.

Mice like to make nests of soft natural permethrin — highly toxic to ticks. The

Tests have shown that this method property against infected ticks and



DAMMINIX

for Control of Lyme Disease



24 Tubes

ACTIVE INGREDIENT: Permethrin

EcoHealth, Inc.

for Control of Lyme Disease Carrying Ticks

DAMMINIX



The host of the adult tick



Feb

~~NOV 28~~ 1988

~~NOV 28~~ 1988

300 / 242160
13 / 1

Mr. Alexander Kovel
Ecohealth, Inc.
33 Mount Vernon Street
Boston, MA 02108

Dear Mr. Kovel:

Subject: Label Amendment
DAMMINIX
EPA Registration No. 56783-1
Your Letters Dated December 1 and 7, 1988

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the reason given below.

- The efficacy data on file for the subject product does not sufficiently demonstrate "control of" deer ticks. If you want to change the phrase "as an aid in the control of" to "for the control of" you must submit data in support of the proposed change.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (H7504C)

57809:I:A-5:LeMaster:LR-10:KENCO:04/03/89:05/12/89:CL:JH:CL

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Alex Tarray
ECOHEALTH, INC.

The Makers of **DAMMINIX**

December 7, 1988

Ms. Christine Dively
U.S. Environmental Protection Agency
Registration Support Branch
Room 724 Crystal Mall Building 2
1921 Jefferson Davis Highway
Arlington, Virginia

Re: Damminix, EPA No. 56783-1

Dear Ms. Dively,

This is a notification of some clarifications in the existing label for the above product in order to remove an inadvertent error that we committed.

At the time of the original registration, (June 22, 1987), we misread the intent of paragraph 3 (f) of George LaRocca's letter accompanying the stamped label.

Paragraph 3 (f) reads:

"On the tube label replace the statement 'Keep out of reach of children' with 'Do not allow Children or Pets to Handle or Play with this Product'".

We mistakenly did not limit this replacement to the tube label, and, because we assumed that all labels should have consistent language, we erroneously made the same replacement on the main label.

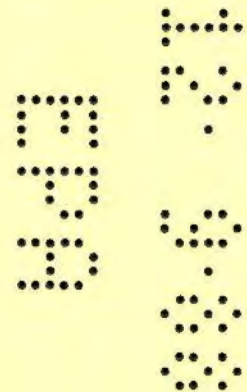
This has just been brought to our attention. We sincerely regret it, and we agree to change the text back to 'Keep out of reach of children' on the very next printing of the label and all subsequent printings of this and any other package size.

Thank you very much for your assistance.

Sincerely,

Alexander Kovel
Alexander Kovel

\Enc.



ECOHEALTH, INC.

The Makers of **DAMMINIX**

December 1, 1988

Ms. Christine Dively
U.S. Environmental Protection Agency
Registration Division TS 767 C
Room 726 Crystal Mall Building 2
1921 Jefferson Davis Highway
Arlington, Virginia

Re: Damminix, EPA No. 56783-1

Dear Ms. Dively,

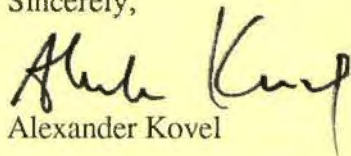
This is a Notification of some clarifications in the existing label for the above product. I am enclosing a copy of the old label and of a printer's proof of the final new label. (I have been waiting for the final printed sheet itself, but the printers keep pushing the deadline back, and I thought it safer to send you the proof text now, since it is identical to the final box label). I am also enclosing form 2070--0060.

To summarize the clarifications:

1. The word "meter(s)" in the existing label has been replaced by "yard(s)" wherever it might have appeared;
2. The introductory language "As an aid in the control of ticks (that may carry Lyme disease)" has been changed to read "For the control of deer ticks, *Ixodes dammini* (that may carry Lyme disease)";
3. The cautionary statement: "Do not allow children or pets to handle or play with this product" has been changed to read "Keep tubes away from children".

Thank you very much for your assistance.

Sincerely,


Alexander Kovel

\Enc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

TO: PM 15
FROM: Reg. Support Br.
SUBJECT: Attached Notification

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

EPA Reg. No. 56783-1
Company Name: ECO HCHL
OPP Identifier 138533
New Label Attached
New CSF Attached ✓

 This is a product name change

 This is an additional brand name

 This is a CSF change permitted under PR Notice 88-6

X This is a label change ^{NOT} permitted under PR Notice 88-6

 File it in the Jacket

 Attach it to the jacket and send to ASG for coding.

 A copy of the label has been sent to ASG for microfiching.

 Mark the label "NOT REVIEWED. Received per PR Notice 88-6"
and send it with the jacket to ASG for microfiching.

 These are final printed labels, previously accepted with
comments. One copy has been sent to ASG for microfiching
marked "NOT REVIEWED in accordance with PR Notice 82-2"

 This covers an amendment previously submitted. You can
strike it off your backlog.

 There is a problem requiring your attention:

 Please handle. This refers to your prior correspondence.

X Please handle as an amendment. This is not covered by
PR Notice 88-6. The registrant has been so informed. *(copy of letter enclosed)*

 Change of address company name Est. No. is being processed.

 This should have been a "Non-notification". The registrant
has been so advised.



United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Application for Pesticide:

☐ Registration
☒ Amendment

OPP Identifier Number

138533

Section I

1. Company/Product Number 56783-1
2. Date December 1, 1988
3. Product Manager ⁽¹⁵⁾ Christine Dively
4. Proposed Classification ☒ General ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)

ECOHEALTH, Inc.
33 Mount Vernon Street
Boston, MA 02108

☐ Check if this is a new address

6. Product Name

DAMMINIX

Section II - Amendment Information

1. Subject
☐ Resubmission in response to Agency letter
☐ Final printed label in response to Agency letter
☒ Other (explain below) Date of Letter

NOTIFICATION

change of label language.
Does not comply with PR
Notice 88-6

H. R. Tansy
(TS-7670)

Section III

1. Material This Product Will Be Packaged In
Child-Resistant Packaging ☐ Yes ☐ No
Unit Packaging ☐ Yes ☐ No
If "Yes," Unit package wgt No. per container
Water-Soluble Packaging ☐ Yes ☐ No
If "Yes," Package weight No. per container
2. Type of Container
☐ Metal
☐ Plastic
☐ Glass
☐ Paper
☐ Other (Specify)
3. Location of Net Contents Information ☐ Label ☐ Container
4. Size(s) of Retail Container
5. Location of Label Directions
☐ On Label
☐ On material accompanying product
6. Manner in Which Label Is Affixed To Product
☐ Lithograph
☐ Paper glued
☐ Stenciled
☐ Other (Specify)

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

Name

Alexander Kovel

Title

President

Telephone No. (Include Area Code)

617-742-2400

6. Date Application Received (Stamped)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

3. Title

President

4. Typed Name

Alexander Kovel

5. Date Signed

Nov 30, 1988

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in three copies. In order to facilitate review, each type of data submitted must be bound separately, and clearly identified on the front cover including the date submitted.

A copy of the application form and a copy of the label should be bound in each separate volume of the data.

All Data For Which Claims of Confidentiality Are Asserted Must Be Submitted, Bound Separately and Clearly Marked As Such

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant Not residing in the United States must have an authorized agent residing in the United States to act for

them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.

JUL 29 1988

845 / 216638
17 / 1

300 / 227609
17 / 2

EcoHealth, Inc.
33 Mount Vernon Street
Boston, MA 02108

Attention: Thomas N. Mather, Ph.D.
Chief Research Scientist

Gentlemen:

Subject: Amendment - Storage Stability Test and Newly
Clarified Statement
DAMMINIX
EPA Registration No. 56783-1
Your Application Dated February 2 and June 28, 1988

The labeling referred to above, submitted in connection with
registration under the Federal Insecticide, Fungicide, and Rodenticide
Act, as amended, is acceptable. A stamped copy is enclosed for your
records.

The information on storage stability was reviewed and found acceptable
and placed in the files for the subject product.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Enclosure

58681:I:Robert:LR-4:KENCO:7/26/88:9/7/88:rw:ek:rw

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

JUL 29 1988

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

56783-1

EPA Reg. No. 56783-1

DAMMINIX

EPA Est. No. 5693 MA1

A TICK TOXICANT

For the reduction of Lyme disease-transmitting ticks and certain other ticks that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

ACTIVE INGREDIENTS :

+* Permethrin 7.4%

INERT INGREDIENTS : 92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2-dichloroethenyl)-2,2-dimethyl cyclopropanecarboxylate

*Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans

Contents: 4.5 grams (approx. 30 cotton balls)

KEEP OUT OF REACH OF CHILDREN

CAUTION

Statement of Practical Treatment

IF SWALLOWED- Contact a physician or Poison Control Center immediately.

IF ON SKIN- Remove contaminated clothing and wash affected areas with plenty of soap and water.

IF IN EYES- Flush eyes with plenty of water. Call a physician if irritation persists.

EcoHealth, Inc., 33 Mt. Vernon Street, Boston, MA 02108

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY

For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these mice become infected and may transmit disease to humans, dogs and horses.

To apply, open both ends of tube. For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 meters in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS AND PATHS: Place tubes within 1 meter of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 meters surrounding the area to be protected should be treated. Replace tube when nesting material is completely removed.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 meters between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Replace tube when nesting material is completely removed.

STORAGE AND DISPOSAL

Store at room temperature. Do not contaminate water, food or feed by storage and disposal.

Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not apply to areas where contamination of fish bearing waters is likely. Do not contaminate water by disposal.

ECOHEALTH, INC.

The Makers of **DAMMINIX**...for *Lyme ticks*

June 28, 1988

Mr. George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
Environmental Protection Agency
401 M. Street SW
Washington, D.C. 20460

Dear Mr. LaRocca,

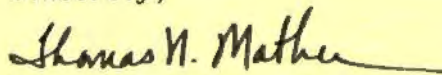
I am writing to inform you of an improvement that we are making in the wording on the label for Damminix (EPA Reg. No. 56783-1). The new language is in keeping with the intended pattern of use of this product and will greatly clarify application information for the consumer.

The newly clarified statement will read as follows:

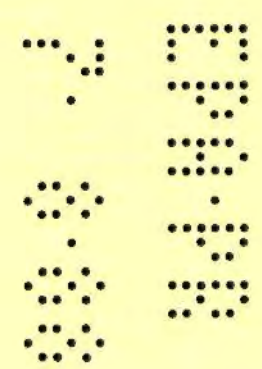
"Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Replace tube when nesting material is completely removed."

This statement is highlighted on the draft label enclosed. We will send you copies of the label containing this new language when they arrive from the printer.

Sincerely,


Thomas N. Mather, Ph.D.
Chief Research Scientist

encl.



245-04-055-cwm

ECOHEALTH, INC.

The Makers of **DAMMINIX**...for Lyme ticks

February 2, 1988

Mr. George T. LaRocca
Product Manager (15)
U.S. Environmental Protection Agency
Room 207 - Bld. 2 - Crystal Mall
1921 Jefferson Davis Hwy.
Arlington, VA 22202

Dear Mr. LaRocca,

We have now completed the 1-year, ambient temperature, storage stability test for **DAMMINIX** (EPA Reg.# 56783-1). I have enclosed 5 copies of the report labeled **63-17 Storage Stability**. Please include this new report on page 2 of section L in the Product Chemistry volume originally submitted to you. This report includes all of the storage stability data, and thus, replaces the existing page 2.

Please call me at (617) 732-2064 if questions arise concerning this report. As before, we thank you for your support of, and interest in our product.

Sincerely yours,

Thomas N. Mather
Thomas N. Mather, Ph.D.
Chief Research Scientist

9538

63-17 STORAGE STABILITY

DAMMINIX 0-DAY (RT), 30-DAY (ET) AND 1 YEAR STORAGE STABILITY TEST RESULTS¹.

Results indicate that no significant breakdown occurred to product when held either at elevated temperatures for 30 days or at ambient temperature for 1 year.

Sample ²	(Permethrin % w/w)		
	0-Day RT ³	30-Day ET ³	1 Year Ambient ⁴
A 2%	2.136	2.062	2.05
	2.157	2.017	2.19
	2.150	2.023	2.27
B 2%	2.041	2.098	2.25
	2.017	2.124	2.08
	2.013	2.132	2.15
C 2%	2.125	2.030	2.16
	2.099	2.048	2.26
	2.084	2.052	1.89
A 8%	7.495	7.388	8.77 ⁵
	7.441	7.483	9.20
	7.462	7.418	8.80
B 8%	7.398	7.575	7.42
	7.418	7.516	7.60
	7.472	7.605	7.37
C 8%	7.421	7.405	5.23 ⁵
	7.443	7.293	5.29
	7.369	7.216	5.49

¹ All analyses were performed by Fairfield American Corp., Frenchtown, NJ.

² Product was originally submitted with a 2% and 8% permethrin designation.

³ Analyzed by HPLC.

⁴ Analyzed by GC.

⁵ Variation in results for the 1 year ambient samples reflect variation in the degree of permethrin adsorption to different individual cotton fibers. Similar variable results are also obtained on some freshly prepared material when analyzed individually. The average result for all nine samples equals 7.24%, a value well within specified limits.

ECOHEALTH, INC.

The Makers of **DAMMINIX**

July 1, 1988

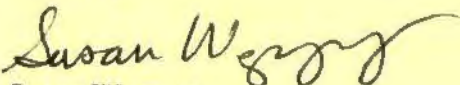
Mr. George T. LaRocca
Product Manager (15)
Insecticide - Rodenticide Branch
Registration Division (TS-767C)
Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

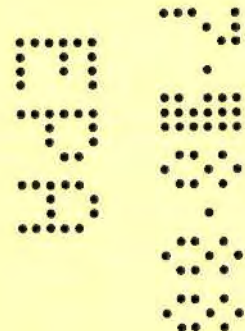
Dear Mr. LaRocca:

Enclosed please find a duplicate of the materials which were sent to you under separate cover this morning.

Thank you for your attention to this matter.

Sincerely,


Susan Wegzyn



REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12066)

1. CHEMICAL NAME

2. IDENTIFYING NUMBER

56783-1

3. ACTION CODE

345

4. ACCESSION NUMBER

TO BE COMPLETED BY PM

5. RECORD NUMBER
216638

6. REFERENCE NUMBER
1

7. DATE RECEIVED (EPA)
2-19-88

8. STATUTORY DUE DATE

9. PRODUCT MANAGER (PM)
HA ROCCA 104

10. PM TEAM NUMBER
15

14. CHECK IF APPLICABLE

☐ Public Health/Quarantine

☐ Minor Use

☐ Substitute Chemical

☐ Part of IPM

☐ Seasonal Concern

☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS
3-11-88

12. PRIORITY NUMBER

13. PROJECTED RETURN DATE

15. INSTRUCTIONS TO REVIEWER

A. HED ☐ Total Assessment - 3(c)(5)

C. ☐ BFSD

☐ Incremental Risk Assessment -
3(c)(7) and/or E.L. Johnson
memo of May 12, 1977.

D. ☐ TSS/RD

E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)

☐ Chemical Undergoing Active
RPAR Review

☐ Chemical Undergoing Active
Registration Standards Review

F. INSTRUCTIONS

16. RELATED ACTIONS

17. 3(c)(1)(D)

☐ Use Any or All Available Information ☐ Use Only Attached Data
☐ Use Only the Attached Data for Formulation and Any or All
☐ Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

☐ TB

☐ EEB

☐ EF

☐ PL

☐ RCB

☐ EFB

☐ CH

☐ BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								
RD/TSS	✓ CHEMISTRY <i>app JPK</i>	1	7/11/88						
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20. ☐ Label Submitted
with Application
Attached

21. ☐ Confidential
Statement of
Formula

22. ☐ Representative
Labels Showing
Accepted Uses
Attached

23. Date Returned to RD
(to be completed by
HED)

24. Include an Original and 4 (four)
Copies of This Completed Form
for Each Branch Checked for
Review.

Reg. # 56783-1
Rec. # _____

Product name DAMINIX

PRODUCT CHEMISTRY CHECKLIST

Please provide the requested information for the following checked items:

1. ☐ Submit the product specific product chemistry and the data matrix for your product. Your product is not sufficiently similar to the product you referenced.
2. On the Confidential Statement of Formula (CSF) please provide the following:
 - ☐ a) Provide pH of product or pH at a specified water dilution.
 - ☐ b) density of product
 - ☐ c) flash point of product
 - *☐ d) flash point of product with the propellant.
 - ☐ e) flame extension of product including flashbacks if noted
 - ☐ f) Provide the upper and lower Certified Limits based on the pure active ingredients rather than the technical or concentrate.
Note that the lower limit of the active must be the same as the label claim.
 - ☐ g) Provide upper and lower Certified Limits of the individually added inerts.
 - ☐ h)
 - ☐ i)
3. ☐ Based on the current CSF dated _____ your product will not meet the label claim for the active ingredient. Please revise the label or the CSF so the information agrees.
4. ☐ Please provide the chemical identity of all components, MSDS and CAS #s of: (two copies reqd)
 - 1)
 - 2)
 - 3)The supplier may contact us directly referencing your file symbol/EPA Reg. # in their response.
For dyes, color index and CAS #s for all components are required. For perfumes and flavoring all chemical components by CAS #s and % in the mixture must be identified. Certify that flavors are of non-food type.
5. ☐ Please update the label Storage and Disposal Statement per PR 83-3 or PR-84-1.
6. ☐ Add a footnote to the label ingredient statement indicating:
Contains petroleum distillates, xylene, xylene range aromatic solvent
7. ☐ Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement. See 40 CFR 162.10
8. ☐ Since your data matrix does not give a dielectrical breakdown voltage, you must add the following to the use directions:
Do not use this product in or on electrical equipment due to the possibility of shock hazard.
9. ☐ Solvent used is not considered an active ingredient so either report it under inert ingredients on the label or provide the registration no. for the source product and justify its insecticidal properties.

9. Data Matrix Requirements

- ☐ a) Statement of Composition - a complete description of the manufacturing/formulation process. Describe equipment used, mixing time, temperature etc.
- ☐ b) Discussion of Formation of [Unintentional] Ingredients - a brief description of impurities formed during the manufacturing/formulation process, in packaging, or during storage. If you do not expect any impurities during these stages, please so state.
- ☐ c) Certification of Limits - upper and lower limits of each active and individually added inert component. The lower limit for the actives, must be the same as the label claim in pure active form.
~~active ingredients.~~
- ☐ d) Analytical Method - provide the methods used to analyze for the active ingredients.
- ☐ e) Color - in common terms.
- ☐ f) Physical State - e.g. solid, liquid, pressurized liquid, etc.
- ☐ g) Odor - in common terms.
- ☐ h) Density - e.g. lbs/gallon for liquids or lbs/cu. ft. for solids.
- ☐ i) pH - provide pH of product or pH of a specified water dilution.
- ☐ j) Oxidizing or Reducing - note these characteristics if any.
- * ☐ k) Flammability - flash point/flame extension.
- ☐ l) Explosibility - note these characteristics if any.
- ☐ m) Storage Stability - the formulated product must be analyzed for its active ingredient at time zero and during a year of storage. The storage should be in warehouse conditions of temperature and humidity and stored in similar containers you will be using in the trade. Note: For the Storage Stability study you cannot reference the concentrate you are using to formulate your product.
- ☐ n) Viscosity - can be expressed in centipoise or centistokes.
- ☐ o) Miscibility - note these characteristics if product is an emulsifiable liquid and mixed with oil.
- ☐ p) Corrosion Characteristics - this information can be noted during the storage stability study.
- ☐ q) Dielectric Breakdown Voltage - for products used near electrical equipment.

approved

No comments

JPK
6-30-88

However we want to know why
Storage Stability was carried out at 27. When
label is 7.4%? We disregard these data
for 27. for this jacket. Rb

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

ECOHEALTH, INC.
33 MOUNT VERNON ST.
BOSTON, MA 02108

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 02/19/88. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

The rejected documents below are identified with numbers which correlate to those taken from your submitted bibliography.

(01)

- * No title page was included for this study.

Studies must be continuously paginated from the title page through the end of the study and all appendices--except for the Confidential Attachment or Supplemental Statement of Confidentiality Claims, if present--even when the study is large enough to span more than one physical volume.

- * You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. See pages 8 and 13 of PR Notice 86-5.

ECOHEALTH, INC.

The Makers of **DAMMINIX**...for Lyme ticks

February 2, 1988

Mr. George T. LaRocca
Product Manager (15)
U.S. Environmental Protection Agency
Room 207 - Bld. 2 - Crystal Mall
1921 Jefferson Davis Hwy.
Arlington, VA 22202

Dear Mr. LaRocca,

rejected
(71)

We have now completed the 1-year, ambient temperature, storage stability test for **DAMMINIX** (EPA Reg.# 56783-1). I have enclosed 5 copies of the report labeled 63-17 Storage Stability. Please include this new report on page 2 of section L in the Product Chemistry volume originally submitted to you. This report includes all of the storage stability data, and thus, replaces the existing page 2.

Please call me at (617) 732-2064 if questions arise concerning this report. As before, we thank you for your support of, and interest in our product.

Sincerely yours,

Thomas N. Mather

Thomas N. Mather, Ph.D.
Chief Research Scientist

09
ECOHEALTH, INC.

The Makers of DAMMINIX...for Lyme ticks

July 2, 1987

George T. LaRocca
Product Manager (15)
Insecticide Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460

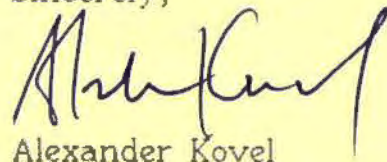
Re: Damminix, EPA Registration No. 56783-1

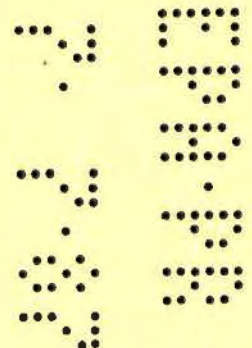
Dear Mr. LaRocca,

Please find enclosed five copies of the final printed labelling for the above product in compliance with your conditional registration.

We very much appreciated the help and consideration you and Ms. Christine Dively of your office provided. Thank you very much.

Sincerely,


Alexander Kovel



DAMMINIX...

for Lyme Disease Carrying Ticks

A TICK TOXICANT

As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

ACTIVE INGREDIENTS:

+ * Permethrin 7.4%

INERT INGREDIENTS:

..... 92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans
3-(2,2-dichloroethenyl)2,

2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and
max. 65% (+/-) trans.

Contents: 4.5 grams

**DO NOT ALLOW CHILDREN OR PETS TO
HANDLE OR PLAY WITH THIS PRODUCT**

CAUTION

Statement of Practical Treatment

IF SWALLOWED—Contact a physician or
Poison Control Center immediately.

IF ON SKIN—Remove contaminated clothing
and wash affected areas with soap and
water.

IF IN EYES—Flush with plenty of water. Call
a physician if irritation persists.

NOT REVIEWED

In accordance with PR Notice 82-2.
Based on draft labelling dated

6-22-87

ECO HEALTH, INC. © 1987

33 Mount Vernon Street

Boston, MA 02108

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA1

U.S. Patent No. 4,662,104

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs and horses.

To apply, open both ends of tube. For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 meters in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 meter of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 meters surrounding the yard area to be protected should be treated. Replace tube when nesting material is completely removed.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 meters between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding woodlot. Placing tubes near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes should be applied at least twice a year: a.) before April 1; b.) before August 1. Replace tube when nesting material is completely removed.

STORAGE AND DISPOSAL:

Store at room temperature. Do not contaminate water, food or feed by storage and disposal.

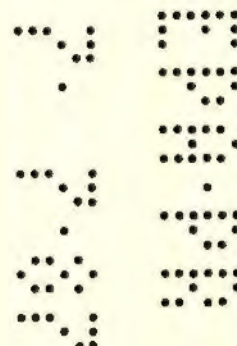
Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water. Do not contaminate water by disposal of wastes or cleaning of equipment.





The Trustees of Reservations
*Conserving the
Massachusetts Landscape*

572 Essex Street
Beverly, Massachusetts
01915

Telephone
617-921-1944

Officers

Henry R. Guild, Jr.
President
Thomas L. P. O'Donnell
Vice President
Hall J. Peterson
Vice President
Carolyn M. Osteen
Secretary
Norton Q. Sloan
Treasurer

Standing Committee

Preston H. Saunders
Chairman
[Redacted] R. Guild, Jr.
Dover
Judy B. Keyes
Concord
George R. Mathey
Ipswich
Thomas L. P. O'Donnell
Hingham
Carolyn M. Osteen
Boston
Hall J. Peterson
Petersham
Susanna LaC. Phippen
Wenham
Norton Q. Sloan
Ipswich
Rush Taggart
Stockbridge
William O. Taylor
Medfield
Marian Thornton
Concord
Herbert W. Vaughan
Salem
Natick
[Redacted] Vogel
[Redacted] Farms

Staff

Frederic Winthrop, Jr.
Director
William C. Clendaniel
Deputy Director
Davis Cherington
*Deputy Director for
Land Conservation*
Elizabeth G. Riggs
*Deputy Director for
Development*
Franklyn J. Stevens
*Deputy Director for
Administration and Finance*

The Trustees of Reservations is a non-profit organization and the largest private owner of conservation land in Massachusetts. It was founded in 1891 to preserve for public use and enjoyment historic places and beautiful tracts of land within the Commonwealth. Today, The Trustees of Reservations owns and manages properties from Berkshire County to Nantucket totaling more than 17,500 acres. The Trustees protects over 5,000 additional acres with conservation restrictions.

June 15, 1987

Mr. George LaRocca
Product Manager No. 15
TS - 766C
Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Dear Mr. LaRocca:

Ecohealth Company has applied for registration from the Environmental Protection Agency for its product "Damminix" used to reduce the abundance of deer ticks.

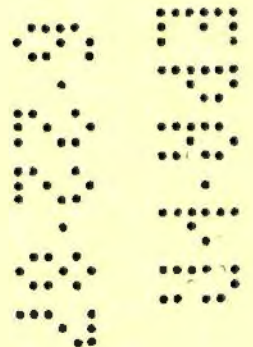
The Trustees of Reservations plans to use Damminix to reduce the risk of Lyme Disease which is carried by deer ticks in Ipswich, Massachusetts. We understand that the first application of Damminix should occur in August, 1987. Since the "tick season" is upon us, we are eager to see Ecohealth Company obtain E.P.A. registration and begin manufacturing Damminix.

If there is anything we can do to hasten the process, please let me know.

Sincerely,

Frederic Winthrop, Jr.
Director

cc: Christine Dively
FW:ig



US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (TS-767) WASHINGTON, DC 20460	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">EPA REGISTRATION NO. 56783-1</td> <td style="width: 50%;">DATE OF ISSUANCE</td> </tr> <tr> <td colspan="2">TERM OF ISSUANCE</td> </tr> <tr> <td colspan="2">NAME OF PESTICIDE PRODUCT DAMMINIX</td> </tr> </table>	EPA REGISTRATION NO. 56783-1	DATE OF ISSUANCE	TERM OF ISSUANCE		NAME OF PESTICIDE PRODUCT DAMMINIX	
EPA REGISTRATION NO. 56783-1	DATE OF ISSUANCE						
TERM OF ISSUANCE							
NAME OF PESTICIDE PRODUCT DAMMINIX							

NOTICE OF PESTICIDE: ☐ REGISTRATION ☐ REREGISTRATION

(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Ecohealth, Inc.
33 Mount Vernon Street
Boston, MA 02108

JUN 22 1987

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit 1-year storage stability data for this product within 15 months from the date of this Notice.
3. Make the labeling changes listed below before you release the product for shipment:
 - a. Add the phrase "EPA Registration No. 56783-1."
 - b. Under "Precautionary Statements" include the following statement after the first sentence in the paragraph:

Contact with the skin may result in temporary numbing and tingling sensations.

☐ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE
	<p>6/22/87</p>

- c. Under the heading ENVIRONMENTAL HAZARDS revise the statements to read:

This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water. Do not contaminate water by disposal of wastes or cleaning of equipment.

- d. Revise the first paragraph on the container and tube label to read as follows:

As an aid in the control of ticks that infest mice and nests of mice found around yards, play areas, parks, brush paths, and woodlands (that may carry Lyme disease).

- e. On the container and tube label replace the sentence beginning "More frequent application beginning . . ." with "Replace tube when nesting material is completely removed."
- f. On the tube label replace the statement "Keep Out of Reach of Children" with "Do Not Allow Children or Pets to Handle or Play with this Product."
4. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Enclosures

CONTAINER LABEL

ACCORDANCE
with COMMENTS
in EPA Letter dated

JUN 22 1987

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
56783-1

DAMMINIX

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA1

A TICK TOXICANT

For the reduction of Lyme disease-transmitting ticks and certain other ticks that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

ACTIVE INGREDIENTS :

+* Permethrin 7.4%

INERT INGREDIENTS : 92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2-dichloroethenyl)-2,2-dimethyl cyclopropanecarboxylate

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans

Contents: 4.5 grams (approx. 30 cotton balls)

KEEP OUT OF REACH OF CHILDREN

CAUTION

Statement of Practical Treatment

IF SWALLOWED- Contact a physician or Poison Control Center immediately.

IF ON SKIN- Remove contaminated clothing and wash affected areas with plenty of soap and water.

IF IN EYES- Flush eyes with plenty of water. Call a physician if irritation persists.

EcoHealth, Inc., 33 Mt. Vernon Street, Boston, MA 02108

CONTAINER LABEL

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY

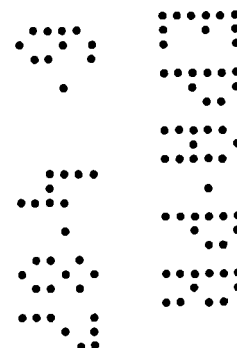
For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing **Lyme disease** and **babesiosis**. Ticks feeding on these mice become infected and may transmit disease to humans, dogs and horses.

To apply, open both ends of tube. For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 meters in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS AND PATHS: Place tubes within 1 meter of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 meters surrounding the area to be protected should be treated. Replace tube when nesting material is completely removed.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 meters between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes should be applied at least twice a year: a) before April 1; b) before August 1. More frequent application, beginning in April and continuing through the summer will improve results.



CONTAINER LABEL

STORAGE AND DISPOSAL

Store at room temperature. Do not contaminate water, food or feed by storage and disposal.

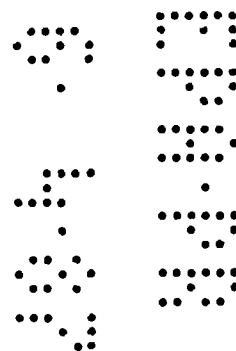
Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

Avoid contact with eyes and skin. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not apply to areas where contamination of fish bearing waters is likely. Do not contaminate water by disposal.



SECONDARY CONTAINER LABEL

DAMMINIX

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA1

A TICK TOXICANT

For the reduction of Lyme disease-transmitting ticks and certain other ticks that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

ACTIVE INGREDIENTS :	
+* Permethrin	7.4%
INERT INGREDIENTS :	92.6%
Total	100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2-dichloroethenyl)-2,2-dimethyl cyclopropanecarboxylate

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans

Contents: 4.5 grams (approx. 30 cotton balls)

KEEP OUT OF REACH OF CHILDREN

CAUTION

IF SWALLOWED- Contact a physician or Poison Control Center

IF ON SKIN- Wash affected areas with soap and water

IF IN EYES- Flush with plenty of water

See box panel for additional precautionary statements.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 22 1987

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
56783-1

DIRECTIONS FOR USE

FOR OUTDOOR APPLICATION ONLY. To apply, open both ends of tube and place tubes flat on the ground in all areas to be treated. Place product in a grid design with not more than 10 yards between tubes in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands.

Product should be applied at least twice a year: a) before April 1; b) before August 1. More frequent application, beginning in April and continuing through the summer will improve results.

STORAGE AND DISPOSAL

Store at room temperature. Do not contaminate water, food or feed by storage and disposal.

This product is completely biodegradable and may be left in the application site or may be collected and put in trash.

EcoHealth, Inc., 33 Mt. Vernon Street, Boston, MA 02108

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

4/30/87
35074 HED

1. CHEMICAL NAME <i>Damminix (Tickbuds)</i>			
2. IDENTIFYING NUMBER <i>56783-R</i>	3. ACTION CODE <i>176</i>	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
			5. RECORD NUMBER <i>194,955</i>
			6. REFERENCE NUMBER <i>1</i>
			7. DATE RECEIVED (EPA) <i>3/26/87</i>
			8. STATUTORY DUE DATE
			9. PRODUCT MANAGER (PM) <i>Lakocca/Direly</i>
			10. PM TEAM NUMBER <i>15</i>

14. CHECK IF APPLICABLE		TO BE COMPLETED BY PCB	
<input type="checkbox"/> Public Health/Quarantine	<input type="checkbox"/> Minor Use	11. DATE SENT TO HED/TSS <i>4-30-87</i>	
<input type="checkbox"/> Substitute Chemical	<input type="checkbox"/> Part of 1PM	12. PRIORITY NUMBER <i>50</i>	
<input type="checkbox"/> Seasonal Concern	<input type="checkbox"/> Review Requires Less Than 4 Hours	13. PROJECTED RETURN DATE <i>7-13-87</i>	

15. INSTRUCTIONS TO REVIEWER		F. INSTRUCTIONS	
A. HED <input type="checkbox"/> Total Assessment - 3(c)(5)	C. <input type="checkbox"/> BFSD	<i>Attn: Ann Stavola</i> <i>Resubm. for rodent repro. data</i> <i>as requested.</i> <i>We are requesting a 30-day</i> <i>turnaround.</i>	
<input type="checkbox"/> Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.	D. <input type="checkbox"/> TSS/RD		
B. SPRD (Send Copy of Form to SPRD PM)	E. <input type="checkbox"/> Other		
<input type="checkbox"/> Chemical Undergoing Active RPAR Review			
<input type="checkbox"/> Chemical Undergoing Active Registration Standards Review			

16. RELATED ACTIONS
to A. Stavola

17. 3(c)(1)(D)		18. REVIEWS SENT TO			
<input type="checkbox"/> Use Any or All Available Information	<input type="checkbox"/> Use Only Attached Data	<input type="checkbox"/> TB	<input type="checkbox"/> EEB	<input type="checkbox"/> EF	<input type="checkbox"/> PL
<input type="checkbox"/> Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.		<input type="checkbox"/> RCB	<input type="checkbox"/> EFB	<input type="checkbox"/> CH	<input type="checkbox"/> BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR, USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS	<i>1</i>							
	RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20. <input type="checkbox"/> Label Submitted with Application Attached	21. <input type="checkbox"/> Confidential Statement of Formula	22. <input type="checkbox"/> Representative Labels Showing Accepted Uses Attached	23. Date Returned to RD (to be completed by HED) <i>6/16/87</i>	24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review. 119
--	--	---	--	--

194955
RECORD NO.

109701
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 05/04/87 OUT 15 JUN 1987

FILE OR REG. NO 56783-R

PETITION OR EXP. NO.

DATE OF SUBMISSION

DATE RECEIVED BY HED 04/30/87

RD REQUESTED COMPLETION DATE 07/13/87

EEB ESTIMATED COMPLETION DATE 07/06/87

RD ACTION CODE/TYPE OF REVIEW 176

TYPE PRODUCT(S) : I, D, H, F, N, R, S Synthetic Pyrethroid

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Damminix (Tick Buster)

COMPANY NAME IVC Corp., Inc.

SUBMISSION PURPOSE Submission of further data in response to
previous EEB review

SHAUGHNESSEY NO. CHEMICAL, & FORMULATION & A.I.

permethrin 7.4%



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

15 JUN 1987

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Review of a Laboratory Study on the Effects on
Reproduction and Neonates of Mice Nesting in Cotton
Treated with 7.4% Permethrin [Damminix (Formerly
Tick Buster), 56783-R]

TO: George La Rocca, PM-15
Insecticides-Rodenticides Branch
Registration Division, TS-767e

FROM: Ann Stavola, Aquatic Biologist *Ann Stavola*
Ecological Effects Branch
Hazard Evaluation Division, TS-769e

THRU: Douglas Urban, Head - Section III *Douglas Urban*
Ecological Effects Branch
Hazard Evaluation Division, TS-769e

THRU: Michael Slimak, Chief *MSlimak 6/14/87*
Ecological Effects Branch
Hazard Evaluation Division, TS-769e

EEB's review of January 9, 1987 regarding the proposed registration of Tick Buster (now called Damminix) stated that the registrant would need to conduct a study to determine any potential risks to which breeding mice could be exposed by using Damminix as nesting material.

The registrant submitted a laboratory study conducted with white mice, Mus musculus, to assess the effects of permethrin - treated cotton used as nest material on the survivability of neonates born in the nests, and the ability of these exposed mice (F₁ generation) to reproduce successfully when they became adults.

Pregnant mice formed nests of the treated cotton, and their offspring (F₁ generation) lived in these nests for 21 days, until they were weaned, separated into groups and subsequently mated.

The results indicated that the F₁ mice born in the treated cotton were not affected by the permethrin either in terms of survivability or dermal abnormalities. The ability of the F₁ mice to reproduce successfully demonstrated that the chemical did not cause any congenital effects that impaired that function.

EEB has determined that the study is acceptable. Based upon the results of this study EEB concludes that the use of Damminix as small rodent nesting material in woodlots to control disease - transmitting ticks will not result in a significant increase in risks to nontarget organisms.

As we mentioned in our earlier review there were several label statements that needed to be clarified. The company should clearly state the following on their label: the minimum distance as well as the maximum distance between the tubes, the maximum number of applications, the time interval between applications, the months the tubes can be applied and, finally, any geographic restrictions.

Superseded by label received 6/4/87

EcoHealth, Inc

27 May 1987

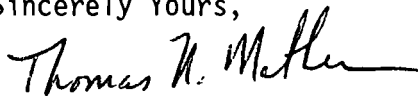
Ms. Christine Dively
Assistant Product Manager (15)
U.S. Environmental Protection Agency
Room 200 - Bld. 2 - Crystal Mall
1921 Jefferson Davis Hwy.
Arlington, VA 22202

Dear Chris,

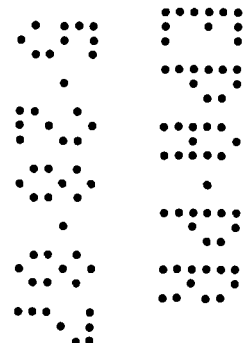
I am sending 5 copies of a revised draft label for **DAMMINIX** (EPA Reg. No. 56783-R), as well as 5 copies of the secondary container (tube) label, for your approval. Revisions were made following our telephone conversation in early April and may not include other changes you have made since then.

Please feel free to call me at (617) 732-2064 should questions or problems arise in your review of this label. We thank you for your prompt attention to this matter.

Sincerely Yours,



Thomas N. Mather, Ph.D.
Chief Research Scientist



ALEXANDER KOVEL, ESQ.

May 20, 1987

Ms. Christine Dively
Assistant Product Manager (PM-15)
Environmental Protection Agency
Crystal Mall, Building 2, Room 200
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Damminix

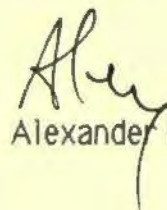
Dear Chris,

I am enclosing the original letter from FMC Corporation authorizing the use of data that we spoke about today. I have also arranged for the formal change of name, (from IVC Corporation to EcoHealth, Inc.), request to be sent to William Shiflet, whose telephone number you gave me this morning.

If you need anything else, please let me know.

We very much appreciate the help you have provided. Thank you.

Sincerely,


Alexander Kovel

33 Mount Vernon Street
Boston, MA 02108
(617) 742-4950

FMC Corporation

Agricultural Chemical Group
2000 Market Street
Philadelphia Pennsylvania 19103
215 299 6000

December 12, 1986



Mr. George T. LaRocca (PM-15)
Registration Division (OPP) (TS-767C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall 2
Arlington, VA 22202

Dear Mr. LaRocca:

Subject: Lyme Tick Buster
EPA Reg. No. 56783-PENDING

FMC Corporation understands that IVC Corporation, Inc. has applied for registration of the subject product and that the subject product contains the active ingredient permethrin. We authorize EPA to consider and use all data contained in the Pounce® Technical insecticide, EPA File No. 279-3013, for the registration of the subject product.

This authorization does not imply any waiver or abdication of our rights in these data or any right to use these data by anyone for use other than specified herein. The Final Rule for "Pesticide Registration and Classification Procedures, Procedures to Ensure Protection of Data Submitter's Rights" provides an original data submitter who has provided EPA with information on an active ingredient that would be subject to "Exclusive Use" protection under FIFRA Section 3(c)(1)(D)(1) would be notified by EPA of each application registration of a product containing that active ingredient at least 30 days before the registration is approved. FMC Corporation does not object to issuance of the subject product registration and therefore, waives the right to receive such notice for the pending application.

Respectfully yours,

A handwritten signature in dark ink, appearing to read 'Rob R. Stewart', is written over a horizontal line.

Robert R. Stewart
Senior Registration Specialist

cc: A. Kovel, IVC Corporation, Inc.

1750a10010asw

yellow

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

IVC CORP., INC.
33 MOUNT VERNON ST.
BOSTON, MA 02108

APR 27 1987

Report of Analysis for Compliance with PR Notice 06-5

Product Name - DAMINIX

EPA Reg. No. - 56783-R

Thank you for your transmittal of 03/24/87. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography. Those problems which are cause for rejection are identified with an asterisk.

In the future please identify the regulatory action (i.e., registration number, experimental permit number, petition number, data call-in, etc.) supported by your submittal.

In the transmittal document, please include a clear list or bibliography of the studies which are being submitted in the data package.

You provided fewer than the required three complete copies of submitted data. In the future, be sure to submit the full number of required copies.

Please include a copy of your transmittal for each copy of your submittal.

The rejected documents below are identified with numbers which correlate to those taken from your submitted bibliography.

(01)

- * The required certification of good laboratory practices required by 40 CFR 160 for studies of this type was omitted.
- * No title page was included for this study.

Studies must be continuously paginated from the title page through the end of the study and all appendices--except for the Confidential Attachment or Supplemental Statement of Confidentiality Claims, if present--even when the study is large enough to span more than one physical volume.

- * You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. See pages 8 and 13 of PR Notice 86-5.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767)

P.S. Note that although we are returning your data for deficiencies noted in the data package a copy of this information has been transmitted to the Ecological Effects Branch to enable them to complete their review on this application for registration.



Ixodes Vector Control

21 March 1987

Mr. George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
Environmental Protection Agency
401 M. Street SW
Washington, D.C. 20460

Dear Mr. LaRocca,

I am sending herein, supplemental data regarding our product (formerly known as **TICK BUSTER**), as requested by reviewers in the Environmental Hazard Division. The study, labeled Study 1A, tested exposure of neonatal mice to 7.4% permethrin-treated cotton nest material. Results clearly indicated that no skin irritation occurred on the hairless mice and no deleterious effects were observed either in mouse survival or reproductive capacity following such an exposure. These data should be inserted into our application for registration, in the section labelled EFFICACY DATA, just after Laboratory Study 1 ending on page 11.

We also request, at this time, that the product name be changed from **TICK BUSTER** to **DAMMINIX...for Lyme ticks**. We feel that this new name better identifies our product for the intended market without making broad claims about its ability to kill all species of ticks. One other change has been made since our initial registration application was made. Although we haven't received new letterhead as yet, the company name was recently changed from IVC Corporation, Inc., and is now **EcoHealth, Inc.** All addresses and telephone numbers have remained the same. Please make note of these changes on our registration application.

We request that this supplemental data receive immediate review so that registration of **DAMMINIX...for Lyme ticks** can be completed as soon as possible. In order for our product to have any effect in reducing the incidence of Lyme disease, it must be applied no later than August 1. Without registration, we are unable to finalize production plans or enlist customers. Thus, in order for us to meet all foreseen production requirements and time lags, registration is needed no later than mid-April, if we are to distribute product in a useful manner in 1987.

We thank you for your cooperation in our effort to protect the public health.

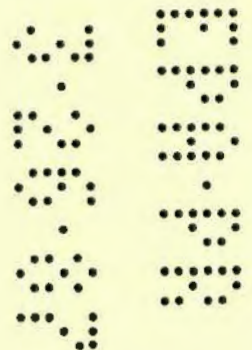
Sincerely Yours,

Thomas N. Mather

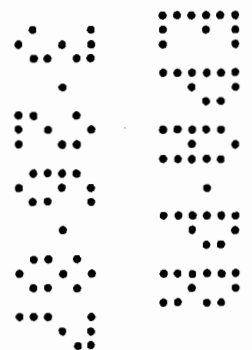
Thomas N. Mather, Ph.D
Chief Research Scientist
EcoHealth, Inc.

Acc. numbers

Product Chemistry	265657
Efficacy	265658



STUDY 1A



1A. Test to evaluate effects of permethrin-treated cotton on neonatal mice.

We evaluated whether permethrin-treated cotton affects survival or reproduction in mice exposed as neonates.

METHODS

Pregnant white mice (*Mus musculus*), due to deliver within 3 days when obtained from Jackson Laboratories, were placed separately in standard 29 X 18 X 13 cm mouse cages containing wood shavings and 4 grams (about 25-30 balls) of cotton for nesting material. A total of 22 of these mice (hereafter called the parental generation, F_0) were divided into 2 equal groups; mice in group 1 were housed with cotton containing 7.4% permethrin, while mice in group 2 were housed with nontreated cotton. The number of offspring (hereafter, the F_1 generation) of these mice was determined by counting at 7 days post-partum. Mice were examined grossly for skin lesions, redness or other abnormalities. These mice, both F_0 and F_1 , remained exposed to the cotton nest material until day 21, when they were completely weaned from their mothers. F_1 mice were again counted and visibly examined for skin abnormalities.

We placed from 2 to 4 F_1 females from each nest (this number depended upon whether or not a nest had 4 females) together with one male from an adjacent nest (ie. females from box 1 were paired with one male from box 2, etc). Mice were held together for about 4 weeks in cages containing woodchips. Thus, permethrin-exposed females mated with similarly exposed males. Nonexposed mice were handled in a like manner. Pregnant F_1 females were separated into standard cages at the time the first F_1 mouse delivered, and were observed daily until all delivered. The number of offspring (hereafter, the F_2 generation) were counted within 12 hours post-partum and again at day 7. These F_2 mice were examined grossly for lesions and abnormalities.

Litter size and survival to weaning of nestlings exposed to 7.4% permethrin were compared to that observed for nonexposed mice using Student's T-test. The reproductive success of animals in the F_1 generation was compared to that of nonexposed mice by using contingency table analysis on the mean litter size of F_1 nestmates.

Cotton used to expose neonatal F_1 mice was tested in a standard bioassay at the time of weaning, following the 21 day exposure. Two nests of treated cotton, and one nontreated cotton nest, were placed together with single *Peromyscus leucopus* that were infested with about 150 larval *Ixodes dammini* for 24 hours. The number of successfully-fed ticks was determined for each bioassay mouse by counting ticks as they detached.

LABORATORY CONDITIONS FOR STUDY 1A

Mice used in this test were held in a large, well-ventilated animal room with constant temperature (70°F) and a 16 hour photoperiod. Cages were held on metal racks so that cages were protected from direct light exposure. Light intensity in the cages was measured to be 20 footcandles using a hand-held light meter (GE type 214). For comparison, daylight illumination was measured to be >1000 footcandles while illumination in a partially-shaded outdoor site was 850 footcandles.

RESULTS

All of the mice formed nests of cotton within 24 hours. These nests were incorporated into hollows dug in the woodchips, and were usually made in the corner of the cages. All F₁ progeny appeared to be delivered into these nests; at least, each litter was covered by the cotton in a nest within 24 hours of delivery.

We counted the number of F₁ offspring produced by pregnant females exposed to treated and nontreated cotton, and determined their survival to weaning (Table 1). The average number of offspring counted at 7 days post-partum was 10.6 (± 1.5) per litter for nontreated mice and 10.3 (± 1.5) per litter for treated mice. No statistical difference was found between treatment and controls ($p = 0.29$). In addition, no mortality was observed among any of the litters between 7 and 21 days after birth. Hairless neonatal mice showed no unusual signs of skin irritation throughout this period. Thus, treatment with 7.4% permethrin-impregnated nest material had no observable effect on the survival of neonatal mice to weaning.

Table 1. 7- and 21-day survival of mice exposed to 7.4% permethrin in nest material at birth compared with similarly-handled nonexposed mice.

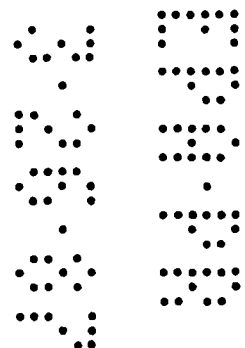
Parent Female	Survival of			
	Permethrin Treated		Nontreated	
	7 days	21 days	7 days	21 days
1	10	10	12	12
2	10	10	10	10
3	12	12	12	12
4	9	9	10	10
5	9	9	8	8
6	9	9	12	12
7	14	14	9	9
8	10	10	11	11
9	10	10	9	9
10	10	10	12	12
11	10	10	12	12

We also determined reproductive success of the F_1 offspring exposed as neonates to either treated or nontreated cotton nests. The number of offspring produced by such treated and nontreated mice are shown in Tables 2A and 2B, respectively. Litter sizes ranged from 2 to 16 offspring for nontreated mice (mean = 11.1; s.d. = 2.8), and 6 to 14 offspring for those exposed as neonates to 7.4% permethrin (mean = 11.0; s.d. = 2.1). Contingency table analysis indicated that no statistical difference existed between treated and nontreated litters of the F_2 generation (Chi-square = 3.097; D.F. = 10; Prob. = .9790). The F_2 offspring of all mice, both from treated and nontreated parents, appeared normal. In addition, no differences were found in their 7-day survival (Chi-square = 3.570; D.F. = 10; Prob. = .9647). Mice, exposed as neonates to 7.4% permethrin-impregnated nest material, had the same reproductive success as did similarly held nontreated mice.

In addition, we determined whether the neonatal mice were exposed to biologically-active permethrin throughout their 3 week exposure. Results of bioassays of treated and nontreated cotton are presented in Table 3. No ticks successfully fed on either *P. leucopus* exposed to treated cotton, while 70% of the ticks initially placed on another mouse that was exposed to nontreated cotton fed successfully.

Table 3. Feeding success of ticks on *P. leucopus* exposed to 3-week old treated (T) and nontreated (NT) cotton used to expose neonates.

Nest	Number of engorged larval ticks				Total
	Days after tick attachment				
	3	4	5	6	
T-5	0	0	0	0	0/150
T-7	0	0	0	0	0/150
NT-1	22	67	12	3	104/150



CONCLUSIONS

Neonatal mice, when exposed from the time of birth until weaning (21 days) to 7.4% permethrin-impregnated nest material, exhibit no reduction in survival or reproductive success when compared with nonexposed mice. In addition, such treated mice develop no apparent skin lesion or irritation. Permethrin in the test cotton remained biologically active throughout the 3 week neonate exposure period. It appears that such permethrin treatment has no adverse effect on neonatally-exposed mice.

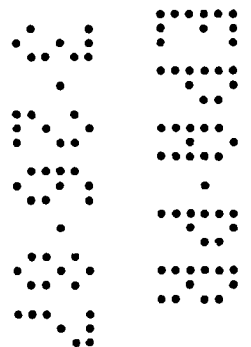


Table 2A. Litter size and 7-day survival of offspring (F_2) from mice exposed to 7.4% permethrin-impregnated nest material² as neonates.

Parental (F_0) No.	Number of F_2 offspring counted for							
	F_1 -1		F_1 -2		F_1 -3		F_1 -4	
	birth	7-day	birth	7-day	birth	7-day	birth	7-day
Treated-1	8	8	11	11	13	13	*	
Treated-2	13	13	12	12	8	8	##	
Treated-3	10	10	10	10	11	11	##	
Treated-4	11	11	13	13	7	7	14	14
Treated-5	10	10	12	12	13	13	10	10
Treated-6	10	10	11	11	12	12	10	10
Treated-7	8	8	12	11	6	6	12	12
Treated-8	12	11	14	14	*		##	
Treated-9	12	12	10	10	8	7	##	
Treated-10	14	14	13	13	8	8	*	
Treated-11	11	11	13	13	14	14	*	

* Failed to become pregnant during experiment.

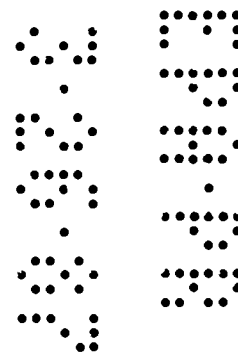
Missing due to insufficient number of females from parental litter.

Table 2B. Litter size and 7-day survival of offspring (F_2) of mice exposed to nontreated cotton nest material as neonates.

Parental (F_0) No.	Number of F_2 offspring counted for							
	F_1 -1		F_1 -2		F_1 -3		F_1 -4	
	birth	7-day	birth	7-day	birth	7-day	birth	7-day
Nontreated-1	11	10	10	10	8	8	12	12
Nontreated-2	10	10	10	10	13	13	##	
Nontreated-3	11	11	11	11	5	5	8	8
Nontreated-4	8	8	11	11	9	9	##	
Nontreated-5	14	14	13	12	16	16	*	
Nontreated-6	11	11	11	11	12	12	14	14
Nontreated-7	16	16	15	15	*		##	
Nontreated-8	12	12	11	11	14	13	13	13
Nontreated-9	2	2	11	9	*		##	
Nontreated-10	12	12	13	13	12	12	10	10
Nontreated-11	11	11	9	9	12	12	*	

* Failed to become pregnant during experiment.

Missing due to insufficient number of females from parental litter.



REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME

Tick Buster (Permethrin)

2. IDENTIFYING NUMBER

56783-R

3. ACTION CODE

175

4. ACCESSION NUMBER

265658

TO BE COMPLETED BY PM

5. RECORD NUMBER

183,805

6. REFERENCE NUMBER

1

7. DATE RECEIVED (EPA)

10/30/86

8. STATUTORY DUE DATE

9. PRODUCT MANAGER (PM)

LaRocca/Dively

10. PM TEAM NUMBER

15

14. CHECK IF APPLICABLE

☒ Public Health/Quarantine

☐ Minor Use

☐ Substitute Chemical

☐ Part of IPM

☐ Seasonal Concern

☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS

11-7-86

12. PRIORITY NUMBER

46

13. PROJECTED RETURN DATE

1-21-87

15. INSTRUCTIONS TO REVIEWER

A. HED ☐ Total Assessment - 3(c)(5)
☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

C. ☐ BFSD
D. ☐ TSS/RD
E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)

☐ Chemical Undergoing Active RPAR Review
☐ Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

This is a reg. appl. for an old chem. - new application method. Prod. Chem. and Eff. attached for your information. No Tox. data was submitted with the application. Please review for Sec. 3 registration purposes.

16. RELATED ACTIONS

17. 3(c)(1)(D)

☐ Use Any or All Available Information ☐ Use Only Attached Data
☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

☐ TB ☐ EEB ☐ EF ☐ PL
☐ RCB ☐ EFB ☐ CH ☐ BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR, USE	Other
HED	TOXICOLOGY	<i>1</i>							
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20. ☐ Label Submitted with Application Attached

21. ☐ Confidential Statement of Formula

22. ☐ Representative Labels Showing Accepted Uses Attached

23. Date Returned to RD (to be completed by HED)

24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

137



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

FEB 25 1987

MEMORANDUM

SUBJECT: EPA Reg. No. 56783-R - Tick Buster: Request for
Toxicology Branch review of new use of permethrin
to control ticks and fleas.

TOX CHEM No.: 652BB
TOX PROJECT No.: 7-0216
Record No.: 183805

FROM: John Doherty *John Doherty* 2/5/87
Toxicology Branch
Hazard Evaluation Division (TS-769)

TO: George LaRocca
Product Manager 15
Registration Division (TS-767)

THRU: Edwin Budd
Section Head
Toxicology Branch
Hazard Evaluation Division (TS-769)

Budd
2/5/87
WFB
2/25/87

Background

The IVC Corporation (Boston, Massachusetts) is seeking to register their product TICK BUSTER which consists of cotton balls impregnated with permethrin. This product represents a novel use of permethrin in that the cotton balls are placed in areas (outdoors) inhabited by rodents particularly mice. The rodents gather the cotton balls and bring them to their nests where the permethrin kills the ticks and fleas.

The registrants letter of application discusses that their product may be especially useful in controlling the tick borne diseases Lyme disease and babesiosis.

No new toxicology data were included in this application. Toxicology Branch (TB) understands that the registrant has the appropriate permission to cite all toxicology data with permethrin in its files to support this registration. This should be verified by Registration Division.

TB Comments

1. TB considers this registration of this product to be toxicologically supported.
2. A copy of the product label is attached. Although no studies with the product TICK BUSTER were submitted, the label signal word (CAUTION) is considered by TB to be appropriate (see 3 below).

The label precautionary statements are not considered adequate at this time. The following comments apply.

- i. TB requests that the registrant verify that inducing vomiting is appropriate in the event that this product is somehow swallowed. The physical nature of this product being in the form of cotton balls may contraindicate vomiting as a first aid measure. For example, the cotton balls may block the windpipe if a person is forced to vomit them. The registrant will have to consult with physicians who are experts in this field to justify inclusion of the instructions to induce vomiting on the label and/or to otherwise devise an appropriate first aid in the event of swallowing this product.
- ii. The precautionary statements should include information that contact with skin may result in transitory numbing and tingling sensations in addition to the instructions to wash hands after contact.

3. The acute toxicity studies normally required to support labelling are not necessary for this product. For example, it would not be practical to attempt to dose rats by gavage or to instill the eyes of rabbits with the cotton balls. The acute dermal LD₅₀ and dermal irritation studies are considered unnecessary because technical permethrin is TOX CAT III (at least) and the formulation would not promote dermal absorption. An inhalation study would not be required based on the use pattern.
4. The toxicity data base previously submitted by the ICI, the FMC and the Burroughs Wellcome Corporations includes batteries of acute, subchronic, chronic, oncogenicity, reproduction, teratology and mutagenicity studies which are considered by TB sufficient to support this proposed use of permethrin.
5. A potential hazard resulting from the use of this product is to non-target species including humans (particularly children) that may contact and in some cases eat the impregnated cotton balls after they have been distributed and left in place.

With respect to humans, an appropriate cautionary statement placed directly on the tube itself should be required. The "Mr. Yuk" symbol would be helpful in discouraging many children from handling this product in the field.

With respect to other species, birds and other nest building species may also take the cotton balls. Thus, TB recommends that this registration request be sent to Ecological Effects Branch (EEB) for review.

11311 Hed
11-7-86

Permethrin - Tick Buster

TO BE COMPLETED BY PM
5. RECORD NUMBER 183,515
6. REFERENCE NUMBER 1
7. DATE RECEIVED (EPA) 10/30/86
8. STATUTORY DUE DATE
9. PRODUCT MANAGER (PM) LaRocca/Diveh
10. PM TEAM NUMBER 15

☐ Review Requires Less Than 4 Hours

13. PROJECTED RETURN DATE

C. ☐ BFSD

D. ☐ TSS/RD

E. ☐ Other

Please review label. The product chemistry and efficacy are included for your information only. No EER data submitted. Registration concerns?

☐ Use Any or All Available Information ☐ Use Only Attached Data
Use Only the Attached Data for Formulation and Any or All
☐ Available Information on the Technical or Manufacturing Chemical.

<input type="checkbox"/> TB	<input type="checkbox"/> EEB	<input type="checkbox"/> EF	<input type="checkbox"/> PL
<input type="checkbox"/> RCB	<input type="checkbox"/> EFB	<input type="checkbox"/> CH	<input type="checkbox"/> BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

183805
RECORD NO.

109701
SHAUGHNESSY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 11/12/86 OUT JAN 9 1987

FILE OR REG. NO. 56783-R

PETITION OR EXP. PERMIT NO. _____

DATE OF SUBMISSION 10/20/86

DATE RECEIVED BY HED 11/07/86

RD REQUESTED COMPLETION DATE 01/21/87

EEB ESTIMATED COMPLETION DATE 01/14/87

RD ACTION CODE/TYPE OF REVIEW 175

TYPE PRODUCT(S): I, D, H, F, N, R, S Synthetic Pyrethroid

DATA ACCESSION NO(S). 265658, 265657

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Tick Buster

COMPANY NAME IVC Corporation, Inc.

SUBMISSION PURPOSE Proposed Registration of Use to Control
Ticks and Fleas

SHAUGHNESSY NO. CHEMICAL & FORMULATION % AI

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

EEB REVIEW

Permethrin Tick Buster

100.0 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

The registrant, IVC Corporation, Inc., is requesting a registration of the permethrin product, Tick Buster, to control ticks carried by the white-footed mouse Peromyscus leucopus.

According to the submission, deer ticks are the principal vector responsible for the transmission of the pathogens causing Lyme disease and human babesiosis in the northeastern and central United States. Immature stages of the tick feed mostly on P. leucopus. This mouse species appears to serve as the principal reservoir for both pathogens.

All life stages of the tick are present throughout large tracts of woodland as well as in residential sites. Because the distribution of the tick is well-dispersed, conventional methods of pesticide application such as spraying are impractical in this case. The registrant believes that by treating the mouse's nesting material with permethrin, which is used to control ticks in the home, the ticks which transmit the pathogens can be effectively reduced in numbers to reduce the incidences of these two diseases.

100.2 Formulation Information

Permethrin*	7.4%
Inert Ingredients:	92.6%
	<u>100.0%</u>

*(3-phenoxyphenyl)methyl(+) cis/trans 3-(2-dichloroethenyl)-2,2-dimethyl cyclopropanecarboxylate

cis/trans ratio: Min 35% (+) cis and max 65% (+) trans

Contents: 4.5 g (approximately 30 cottonballs)

100.3 Application Methods, Directions, Rates

Permethrin-impregnated mouse nest material kills ticks and fleas attached to mice and present in the nest.

For the control of disease-transmitting and other ticks and fleas around yards and in woodlots.

FOR OUTDOOR APPLICATION ONLY

For the control of ticks and other ectoparasites associated with rodents that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and transmit disease to humans, dogs, and horses. The cottonballs enclosed in cardboard dispensing tubes are impregnated with permethrin and are intended as bedding that rodents will remove to their nests. Treatment of nests does not harm rodents but kills disease-transmitting ticks, both on the rodents and in their nests.

To apply, discard plastic endcaps. For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 m in any direction. Treatment should be limited to areas inhabited by rodents, and need not include mown lawns or open grasslands. Tubes should be positioned so that rodents have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 m of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever rodents may reside. For complete coverage, all brush-covered or wooded areas within 50 m surrounding the yard area to be protected should be treated. Replace tube when nesting material is completely removed.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 m between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding woodlot. Placing tubes near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes should be applied at least twice a year: before April 1 and before August 1. More frequent application, beginning in April and continuing through the summer, will improve results.

Note: Do not remove cottonballs from inside of tube. Contact of this material with skin may cause irritation.

100.4 Target Organisms

Deer ticks (Ixodes dammini)
Fleas
Other ectoparasites

100.5 Precautionary Labeling

This product is extremely toxic to fish. Do not apply to areas where contamination of fish-bearing waters is likely. Do not contaminate water by disposal.

101.0 Hazard Assessment

101.1 Discussion

The permethrin product Tick Buster will be used to control ticks and other ectoparasites on the white-footed mouse Peromyscus leucopus. Cottonballs enclosed in cardboard tubes will be impregnated with permethrin, and the tubes will be placed in wooded areas to be accessible to the mice. The cotton will be carried by the mice to their nests to be used as nesting material. The pesticide in the cotton will kill the disease-transmitting ticks on the mice and in their nests.

Permethrin is fully registered for use on many agricultural crops and around the home and garden for control of many pests including fleas and ticks. The application rates to agricultural crops range from 0.05 to 0.2 lb ai/A.

101.2 Likelihood of Adverse Effects to Nontarget Organisms

Permethrin is very highly toxic to aquatic organisms as the LC₅₀ values for freshwater fish and invertebrates range from 0.32 to 9.8 ppb. However, permethrin is relatively nontoxic to birds and moderately to relatively nontoxic to mammals. The avian LC₅₀ and LD₅₀ values for the mallard duck and bobwhite quail are > 10,000 ppm and > 4640 mg/kg, respectively. The mammalian acute oral toxicity values range from 400 to 8000 mg/kg for the rat and from 500 to 700 mg/kg for the mouse. The acute dermal LD₅₀ value for the mouse is > 2500 mg/kg indicating permethrin is relatively nontoxic by this route of exposure.

By enclosing the permethrin-soaked cottonballs in cardboard tubes and placing them at a density of 48 tubes per acre the total active ingredient per acre is only 0.04 lb/A, which is less than the rates already approved for use on a number of agricultural crops. Furthermore, it is very unlikely that the permethrin would enter aquatic systems from this method of application. Therefore, the use of permethrin in Tick Buster will not be unacceptably hazardous to aquatic organisms.

However, Peromyscus will be exposed to the permethrin by carrying the treated cotton to their nests in their mouths and also by nesting in the material and coating

their fur with the chemical. In addition, neonates born in nests containing this material will be more susceptible to dermal contamination since they do not have a protective coat of fur.

Some of the efficacy data that were submitted in EPA Accession No. 265658 indicate that permethrin's toxic activity against ticks persists for 1 to 2 months in the field and up to 6 months over winter. In addition, the fur of mice became impregnated with permethrin which maintained its acaricidal activity for at least 2 days after the mice were removed from the study site. These efficacy testing results indicate that there is a long-term exposure of Peromyscus to permethrin which could be hazardous.

In order to learn if the amount of permethrin to which each mouse could be exposed would be dermally toxic, the amount of permethrin with which each mouse would come into contact was calculated. (The calculations are attached to this review.) In summary, if the percent active ingredient of permethrin in this product is 7.4%, each tube contains 30 cottonballs that weigh a total of 4.5 g, and there are 48 tubes distributed in an acre, the amount of permethrin available per acre is 15.98 g. In a field study (Study 2) submitted by the registrant, mice removed an average of 25% and 30% of the cotton from tubes in grids measuring 0.36 ha over a 3-week period. Each tube contained 10 g of cotton; therefore, 2.5 to 3.0 g of cotton were removed from each tube. If we assume that 3 g is the amount of cotton normally removed from each dispensing tube, then 0.223 g of permethrin will be removed from a tube containing 4.5 g treated with 7.4% permethrin. The amount of permethrin taken by mice per acre is 10.7 g. The density of Peromyscus is 10 to 20 individuals per acre (L. Turner, Pers. Comm.). Therefore, an individual mouse will take 0.54 to 1.07 g permethrin. The acute dermal LD₅₀ value is \geq 2500 mg/kg body weight. Since a mouse weighs 25 g the LD₅₀ per mouse is 62.5 mg/mouse, which is considerably less than the amount of permethrin to which each mouse can be exposed (540 to 1070 mg). According to this exposure model, Peromyscus will be exposed to amounts of permethrin that can be hazardous.

There are some flaws with this exposure model. It does not account for the amount of permethrin absorbed through the mouth as the mice carry the cotton to their nests. It assumes that all the cotton removed from the tubes is taken solely by P. leucopus, and all the missing cotton reaches their nests. However, the model still provides a means to look at potential exposure.

Label statements do warn that the product can cause skin irritations. If it can irritate human skin that comes into contact with the treated cotton for a short period of time, what are the effects on small rodents, including neonates, that will nest in it?

In a field study (Study 2) submitted by the registrant, the effects of the treated cotton on mouse populations were assessed. Tubes containing 10 g of permethrin-treated cotton (5%) were placed 10 m apart in 7 x 7 and 5 x 10 grid patterns. Mice were live-trapped in each site at 3-week intervals from May through September 1985. The increase in the number of mice captured in treated and nontreated sites increased 329% and 302%, respectively. A total of 38% of the mice captured in nontreated sites weighed 19 g or less, whereas 47% of the mice captured in treated sites were in that weight class. This difference is not statistically significant.

There appear to be several weaknesses with this study. A sampling interval of 3 weeks is too long; the preferred interval is 1 week or less in order to minimize the influences of immigration and emigration. The method used to estimate population from the rate of capture is not described (e.g., catch effort, mark-recapture). Since the interval between samplings is long, how were the effects of immigration and emigration taken into account? In addition to this information the raw data, including numbers of mice caught per trap per sampling time, age classes of mice caught, lengths of the pre- and postexposure periods and amount of cotton removed from each tube at each sampling period must be given. If the experimental design of the study is flawed, it is very likely this study cannot be used to support the registration of this product. Therefore, we do not have sufficient data to determine the effects on small rodent populations from Tick Buster.

101.3 Endangered Species Considerations

There are no endangered small rodents living in wooded areas around residential areas.

104.4 Adequacy of Toxicity Data

As mentioned in Section 101.2 the field study (Number 2 by Mather et al.) may have significant deficiencies to preclude it from supporting this product. The raw data and explanation of the experimental design and field procedures as described above must be submitted for us to do a full analysis of this study.

Should this study prove to be unacceptable, a laboratory study can be done in lieu of another field study. The basic premise of the laboratory study would be for mice to nest in cotton treated with Tick Buster at the rate specified on the label and observe the mice through one generation so neonates as well as adults are exposed. Since this type of study is not standardized, the registrant is advised to consult with EEB prior to its initiation.

101.5 Adequacy of Labeling

There are several deficiencies with the label.

- X 1) The submission indicates that the disease problems are most prevalent in the northeastern and central United States yet there is no label statement concerning geographic restrictions. If the registrant wants to limit use of this product to these regions of the country the label must clearly name only those States in which it will be used.
- X 2) The distance between tubes is not to exceed 10 m in any direction. No minimum distance is given. If the tubes are to be placed 10 m apart, it should be clearly stated.
- X 3) The tubes are to be applied at least twice a year, but they can be applied more often. A maximum number of applications and the time interval between applications should be stated. The statement "Beginning in April and continuing through the summer" is vague.

103.0 Conclusions

EEB has reviewed the proposed registration of the permethrin product, Tick Buster, for use as a small rodent nesting material in woodlots to control disease transmitting ticks. EEB is unable to complete the risk assessment for this use because pertinent ecological effects data are lacking. In order to assess the risks for this use, EEB requires the following:

- 1) Explanation and full description of the experimental design, field procedures and raw data (as described in Section 101.2) for the field study by Mather et al on the effects of Tick Buster on wild mouse populations.

- 2) If the study is insufficient a laboratory study on the effects of cotton treated with Tick Buster on Peromyscus leucopus through one generation is required. Prior to initiating this study the registrant is advised to consult with EEB.

Ann Stavola 1/9/87

Ann Stavola
Aquatic Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

Doug Urban 1/4/87
Doug Urban
Section Head
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

Michael Slimak 1/9/87
Michael Slimak
Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

Calculations

7.4% permethrin per weight of cotton
 $(0.074)(4.5 \text{ g cotton/tube}) = \underline{0.333 \text{ g permethrin/tube}}$

48 tubes/acre
 $0.33 \text{ g permethrin/tube} \times 48 \text{ tubes/A} = \underline{15.98 \text{ g permethrin/A}}$

Field Test: 25% to 30% cotton taken from tubes containing 10 g cotton per tube. Therefore, 2.5 to 3 g cotton taken per tube.

Assume 3 g is amount of cotton normally taken from tubes by mice. Then:

$(3 \text{ g}/4.5 \text{ g})(0.333 \text{ g permethrin/tube}) = \underline{0.223 \text{ g permethrin}}$
taken from each tube.

$(0.223 \text{ g permethrin/tube})(48 \text{ tubes/A}) = 10.7 \text{ g permethrin}$
taken from each acre.

Assume 10 to 20 mice per acre:

$(10.7 \text{ g permethrin/A})/(10 \text{ to } 20 \text{ mice/A}) =$
0.54 to 1.07 g permethrin taken by each mouse

Acute dermal LD₅₀ > 2500 mg/kg body weight
1 mouse weighs 25 g

Therefore, LD₅₀/mouse > 62.5 mg/mouse

Attachment

TICK BUSTER

56783-R, IVC Corp. Boston, Ma

Would put permethrin impregnated cotton ^{balls} in deer mouse's habitat. Mice would collect this cotton to use as nest material + would control disease vector ticks in the process.

Applicant claims that this "simply represents a new application method" and is not "a new use pattern". This contention is nonsense. It is a new use pattern.

Application Method

Plastic tubes containing impregnated cotton balls would be placed at intervals of 10 m. or less in deer mouse habitat.

Tubes could be set ground in open in "all brush-covered and wooded areas to be treated." Should not be placed on "mown lawns" but may be placed near lawns, in flower beds, under bushes and along fences, wherever rodents may reside. May also be placed in wood lots, at ~~the~~ intervals ≤ 10 m, especially "... near thickets or rotting logs." Should be placed "at least twice a year: a) before April 1; b) before August 1." — This suggests some ~~permanent~~ persistence.

Cotton balls "may cause skin irritation."

→ Strong possibility that kids will find tubes + "disturb" their contents.

- Should they be dyed? Warnings on tube?

- Might want to use ~~sturdy~~ sturdier, secure stations in places near where children might find tubes.

Could probably go Sec. 18 on this thing right away if we had an application. Lyme Disease is nothing to fool around with.

With their Jazzy name (TICK BUSTER), one wonders, however, how much of this interest is in making a buck rather than in disease abatement. The county health dept. should maybe be the agent dispensing this product.

Human safety questions will have to be addressed

Approach is biologically plausible. Data reported are consistent with claims ^{implied} ~~made~~ for product

(Could say "Aids in the control ~~B~~ ^{deer} of ticks which may carry Lyme Disease)

Bill Jacobs
1/5/87

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME

Tick Buster (Permethrin)

2. IDENTIFYING NUMBER

56783-R

3. ACTION CODE

175

4. ACCESSION NUMBER

265658

TO BE COMPLETED BY PM

5. RECORD NUMBER

183,805

6. REFERENCE NUMBER

7. DATE RECEIVED (EPA)

10/30/86

8. STATUTORY DUE DATE

9. PRODUCT MANAGER (PM)

LaRocca/Dively

10. PM TEAM NUMBER

15

14. CHECK IF APPLICABLE

☒ Public Health/Quarantine

☐ Minor Use

☐ Substitute Chemical

☐ Part of IPM

☐ Seasonal Concern

☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS

12. PRIORITY NUMBER

13. PROJECTED RETURN DATE

15. INSTRUCTIONS TO REVIEWER

A. HED ☐ Total Assessment - 3(c)(5)
☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

C. ☐ BFSD
D. ☐ TSS/RD
E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)

☐ Chemical Undergoing Active RPAR Review
☐ Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

Please review for adequacy to support registration.

16. RELATED ACTIONS

3(c)(1)(D)

☐ Use Any or All Available Information ☐ Use Only Attached Data
☐ Use Only the Attached Data for Formulation and Any or All
☐ Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

☐ TB ☐ EEB ☐ EF ☐ PL
☐ RCB ☐ EFB ☒ CH ☐ BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY								
	EFFICACY <i>RL/TSM 1/12/87 10 Min.</i>								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20. ☐ Label Submitted with Application Attached

21. ☐ Confidential Statement of Formula

22. ☐ Representative Labels Showing Accepted Uses Attached

23. Date Returned to RD (to be completed by HED)

24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

153

EFFICACY REVIEW

DATE: IN 11-7-86 OUT 1-12-87

FILE OR REG. NO. 56783-R

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED October 20, 1986

DATE OF SUBMISSION October 20, 1986

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): (I) D, H, F, N, R, S

DATA ACCESSION NO(S). 265658; Record Number: 183805; Action Code: 175

PRODUCT MGR. NO. 15- LaRocca/Dively

PRODUCT NAME(S) Tick Buster

COMPANY NAME IVC Corporation, Incorporated

SUBMISSION PURPOSE To apply for registration of a product to control
populations of infective ticks responsible for trans-
mission of diseases, on mice and in their burrows.

CHEMICAL & FORMULATION Permethrin 7.4%
(impregnated on cotton balls at 80mg a.i./kg cotton)

CONCLUSIONS & RECOMMENDATIONS The data are adequate to support registra-
tion of a claim for reduction of populations of infective ticks involved in
transmission of Lyme disease and babesiosis around yards and in woodlots by
controlling ticks attached to mice and/or present in their burrows. Since
this reviewer is unfamiliar with the biology of field mice, Dr. William Ja-
cobs was consulted as to the feasibility and practicality of such a product.
His comments are attached, and of special note are his conclusions as to this
being a new use despite registrant's position to the contrary; that data re-
ported are consistent with claims implied for product; and that if disease
abatement rather than sales is the primary objective, distribution might better
be handled by county health departments than individual landowners. Also, his
recommendations as to using sturdier, secured stations instead of tubes in places
where children were apt to find them and the possibility of securing a Section 18 in
less time than regular registration due to the nature of the disease threat.

RL Vernal, McFarland, IRB-TSS

RECORD OF COMMUNICATION

☒ PHONE CALL ☐ DISCUSSION ☐ FIELD TRIP ☐ CONFERENCE
☐ OTHER (SPECIFY)

(Record of item checked above)

TO:

Alex Kovel

FROM:

Chris Dively

DATE

Feb. 23, 1987

TIME

SUBJECT

Tickbaster

SUMMARY OF COMMUNICATION

I Provided Mr. Kovel with the results of the EEB review with a request for additional mouse reproduction data.

CONCLUSIONS, ACTION TAKEN OR REQUIRED

Mr. Kovel will forward the data to EPA ASAP.

INFORMATION COPIES

TO:

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME <div style="text-align: center; font-size: 1.2em;">Tickbuster - PERMETHRIN</div>											
2. IDENTIFYING NUMBER <div style="text-align: center; font-size: 1.2em;">56783-R</div>		3. ACTION CODE <div style="text-align: center; font-size: 1.2em;">176</div>		4. ACCESSION NUMBER		TO BE COMPLETED BY PM					
						5. RECORD NUMBER <div style="text-align: center; font-size: 1.2em;">188,063</div>					
						6. REFERENCE NUMBER <div style="text-align: center; font-size: 1.2em;">1</div>					
						7. DATE RECEIVED (EPA) <div style="text-align: center; font-size: 1.2em;">12/15/86</div>					
						8. STATUTORY DUE DATE					
						9. PRODUCT MANAGER (PM) <div style="text-align: center; font-size: 1.2em;">Lalocca/Dively</div>					
						10. PM TEAM NUMBER					
14. CHECK IF APPLICABLE						TO BE COMPLETED BY PCB					
<input type="checkbox"/> Public Health/Quarantine <input type="checkbox"/> Minor Use						11. DATE SENT TO HED/TSS					
<input type="checkbox"/> Substitute Chemical <input type="checkbox"/> Part of IPM						12. PRIORITY NUMBER					
<input type="checkbox"/> Seasonal Concern <input type="checkbox"/> Review Requires Less Than 4 Hours						13. PROJECTED RETURN DATE					
15. INSTRUCTIONS TO REVIEWER					F. INSTRUCTIONS						
A. HED <input type="checkbox"/> Total Assessment - 3(c)(5) <input type="checkbox"/> Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977. B. SPRD (Send Copy of Form to SPRD PM) <input type="checkbox"/> Chemical Undergoing Active RPAR Review <input type="checkbox"/> Chemical Undergoing Active Registration Standards Review					C. <input type="checkbox"/> BFS D. <input type="checkbox"/> TSS/RD E. <input type="checkbox"/> Other <div style="font-size: 1.2em; margin-top: 10px;">Please review Storage Stability Data 30-day accelerated study</div>						
16. RELATED ACTIONS											
17. 3(c)(1)(D)					18. REVIEWS SENT TO						
<input type="checkbox"/> Use Any or All Available Information <input type="checkbox"/> Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.					<input type="checkbox"/> TB <input type="checkbox"/> EEB <input type="checkbox"/> EF <input type="checkbox"/> PL <input type="checkbox"/> RCB <input type="checkbox"/> EFB <input type="checkbox"/> CH <input type="checkbox"/> BFS						
19. To		TYPE OF REVIEW		NUMBER OF ACTIONS							
				Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED		TOXICOLOGY									
		ECOLOGICAL EFFECTS									
		RESIDUE CHEMISTRY									
		ENVIRONMENTAL DATA									
RD/TSS	X	CHEMISTRY, Product		1							
		EFFICACY									
		PRECAUTIONARY LABELING									
BFS		ECONOMIC ANALYSIS									
20. <input checked="" type="checkbox"/> Label Submitted with Application Attached		21. <input type="checkbox"/> Confidential Statement of Formula		22. <input type="checkbox"/> Representative Labels Showing Accepted Uses Attached		23. Date Returned to RD (to be completed by HED)		24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.			

IVC

Ixódes Vector Control

Mr. George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
Environmental Protection Agency
401 M. Street SW
Washington, D.C. 20460

15 December, 1986

Dear Mr. LaRocca,

I have enclosed results from the 30 day accelerated stability study for **LYME TICK BUSTER** (EPA # 56783-R). Please replace page 2 of section L in the product chemistry portion of our registration application with this new page labelled 63-17 STORAGE STABILITY.

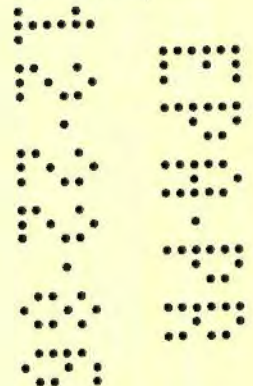
These results were generated by Fairfield American Corporation using material prepared by Dr. Thomas Mather of IVC Corporation. For the stability evaluation, Dr. Mather prepared hand-made batches using the same protocol he had followed to prepare the numerous batches required to generate the efficacy data reported in our application.

We hope that these data will satisfactorily complete our application, and we look forward to the completion of your review. In the meantime, if additional questions arise, please contact either Dr. Mather (617-732-2064) or myself (617-742-4950).

*Informed Mr. Kovel
that Storage Stability
Study was needed
Telephone conv. 12/10/86*

Sincerely Yours,

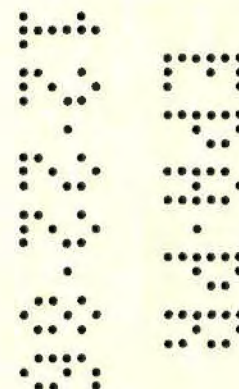
Alexander Kovel
Alexander Kovel
President, IVC Corporation, Inc.



63-17 STORAGE STABILITY

HARVARD MOUSE TUBES (TICK BUSTERS) 0-DAY RT & 30-DAY ET SST (2 & 8% PERMETHRIN)
(Permethrin % w/w)

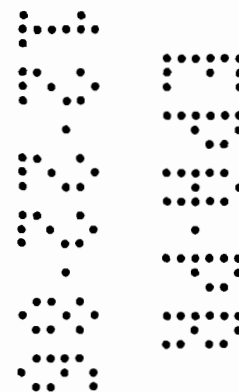
<u>2 % Tubes</u>			<u>8 % Tubes</u>		
<u>Sample</u>	<u>0-Day RT</u>	<u>30-Day ET</u>	<u>Sample</u>	<u>0-Day RT</u>	<u>30-Day ET</u>
A	2.136	2.062 ✓	A	7.495	7.388
	2.157	2.017 ✓ 2.32		7.441	7.483
	2.150	2.023		7.462	7.418
B	2.041	2.098	B	7.398	7.575
	2.017	2.124		7.481	7.516
	2.013	2.132		7.472	7.605
C	2.125	2.030 ✓	C	7.421	7.405
	2.099	2.048		7.443	7.293
	2.084	2.052		7.369	7.216
Average:	2.091	2.065	Average:	7.442	7.433
% Rec'y:		98.8	% Rec'y:		98.0



63-17 STORAGE STABILITY

HARVARD MOUSE TUBES (TICK BUSTERS) 0-DAY RT & 30-DAY ET SST (2 & 8% PERMETHRIN)
(Permethrin % w/w)

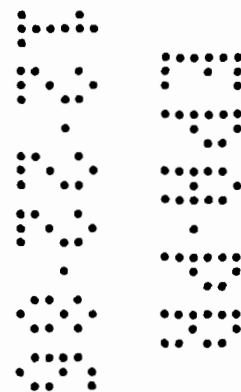
<u>2 % Tubes</u>			<u>8 % Tubes</u>		
<u>Sample</u>	<u>0-Day RT</u>	<u>30-Day ET</u>	<u>Sample</u>	<u>0-Day RT</u>	<u>30-Day ET</u>
A	2.136	2.062	A	7.495	7.388
	2.157	2.017		7.441	7.483
	2.150	2.023		7.462	7.418
B	2.041	2.098	B	7.398	7.575
	2.017	2.124		7.481	7.516
	2.013	2.132		7.472	7.605
C	2.125	2.030	C	7.421	7.405
	2.099	2.048		7.443	7.293
	2.084	2.052		7.369	7.216
Average:	2.091	2.065	Average:	7.442	7.433
% Rec'y:		98.8	% Rec'y:		98.0



63-17 STORAGE STABILITY

HARVARD MOUSE TUBES (TICK BUSTERS) 0-DAY RT & 30-DAY ET SST (2 & 8% PERMETHRIN)
(Permethrin % w/w)

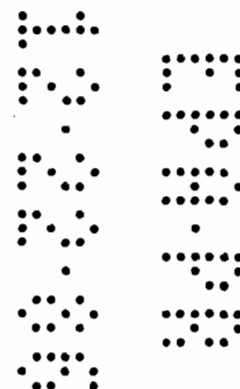
<u>2 % Tubes</u>			<u>8 % Tubes</u>		
<u>Sample</u>	<u>0-Day RT</u>	<u>30-Day ET</u>	<u>Sample</u>	<u>0-Day RT</u>	<u>30-Day ET</u>
A	2.136	2.062	A	7.495	7.388
	2.157	2.017		7.441	7.483
	2.150	2.023		7.462	7.418
B	2.041	2.098	B	7.398	7.575
	2.017	2.124		7.481	7.516
	2.013	2.132		7.472	7.605
C	2.125	2.030	C	7.421	7.405
	2.099	2.048		7.443	7.293
	2.084	2.052		7.369	7.216
Average:	2.091	2.065	Average:	7.442	7.433
% Rec'y:		98.8	% Rec'y:		98.0



63-17 STORAGE STABILITY

HARVARD MOUSE TUBES (TICK BUSTERS) 0-DAY RT & 30-DAY ET SST (2 & 8% PERMETHRIN)
(Permethrin % w/w)

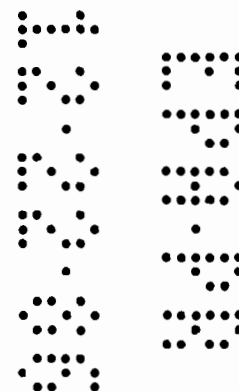
<u>2 % Tubes</u>			<u>8 % Tubes</u>		
<u>Sample</u>	<u>0-Day RT</u>	<u>30-Day ET</u>	<u>Sample</u>	<u>0-Day RT</u>	<u>30-Day ET</u>
A	2.136	2.062	A	7.495	7.388
	2.157	2.017		7.441	7.483
	2.150	2.023		7.462	7.418
B	2.041	2.098	B	7.398	7.575
	2.017	2.124		7.481	7.516
	2.013	2.132		7.472	7.605
C	2.125	2.030	C	7.421	7.405
	2.099	2.048		7.443	7.293
	2.084	2.052		7.369	7.216
Average:	2.091	2.065	Average:	7.442	7.433
% Rec'y:		98.8	% Rec'y:		98.0



63-17 STORAGE STABILITY

HARVARD MOUSE TUBES (TICK BUSTERS) 0-DAY RT & 30-DAY ET SST (2 & 8% PERMETHRIN)
(Permethrin % w/w)

<u>2 % Tubes</u>			<u>8 % Tubes</u>		
<u>Sample</u>	<u>0-Day RT</u>	<u>30-Day ET</u>	<u>Sample</u>	<u>0-Day RT</u>	<u>30-Day ET</u>
A	2.136	2.062	A	7.495	7.388
	2.157	2.017		7.441	7.483
	2.150	2.023		7.462	7.418
B	2.041	2.098	B	7.398	7.575
	2.017	2.124		7.481	7.516
	2.013	2.132		7.472	7.605
C	2.125	2.030	C	7.421	7.405
	2.099	2.048		7.443	7.293
	2.084	2.052		7.369	7.216
Average:	2.091	2.065	Average:	7.442	7.433
% Rec'y:		98.8	% Rec'y:		98.0



Rg 56783-R
Till Buster Permethrin
IVC Corp. Inc

PM: I have reviewed only storage
stability data as requested.

The storage stability data for
2% & 7.4% are acceptable
for 30 days studies

The label is for 7.4% why do we
have data for 2% in the jacket?

One year h.T storage stability
data are requested.

2/2/87

Byron Canale



U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAM (TS-767)
WASHINGTON, D.C. 20460

Form Approved OMB No. 2000-0012

Please read instructions
on reverse before com-
pleting.

APPLICATION FOR PESTICIDE:

☒ REGISTRATION
☐ AMENDMENT

A

SECTION I

1. COMPANY/PRODUCT NO.

56483-R

2. DATE

October 20, 1986

3. PRODUCT MANAGER

G. LaRocca (PM 15)

4. PROPOSED CLASSIFICATION

☒ GENERAL

☐ RESTRICTED

5. NAME AND ADDRESS OF APPLICANT (Include ZIP Code)

IVC Corporation, Inc.
33 Mt. Vernon Street
Boston, MA 02108

☐ CHECK IF THIS IS A NEW ADDRESS

6. PRODUCT NAME

TICK BUSTER

SECTION II

1. SUBJECT OF AMENDMENT

☐ RESUBMISSION IN RESPONSE TO AGENCY LETTER DATED _____

☐ FINAL PRINTED LABEL IN RESPONSE TO AGENCY LETTER DATED _____

☐ OTHER (explain below)

SECTION III

1. WILL THIS PRODUCT BE PACKAGED IN:

CHILD-RESISTANT PACKAGING ☐ YES ☒ NO

UNIT PACKAGING ☐ YES ☒ NO

If YES, unit pkg. wt. _____ No. per container _____

WATER-SOLUBLE PACKAGING ☐ YES ☒ NO

If YES, pkg. wt. _____ No. per container _____

2. TYPE OF CONTAINER

☐ METAL

☐ PLASTIC

☐ GLASS

☒ PAPER

☐ OTHER (Specify)

3. LOCATION OF NET CONTENTS

☒ LABEL

☐ CONTAINER

4. SIZE(S) OF RETAIL CONTAINER

1 tube--4.5 grams net contents

5. LOCATION OF LABEL DIRECTIONS

☒ ON LABEL

☐ ON MATERIAL ACCOMPANYING PRODUCT

6. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT

☐ LITHOGRAPH

☐ OTHER (Specify)

☒ PAPER GLUED

☒ STENCILED

SECTION IV

1. CONTACT POINT (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

NAME

Alexander Kovel

TITLE President, IVC Corporation, Inc.

TELEPHONE NO. (Include Area Code)

617-742-4950

2. SIGNATURE

Alexander Kovel

3. TITLE

President

4. TYPED NAME

Alexander Kovel

5. DATE SIGNED

10/20/86

6. DATE APPLICATION RECEIVED (Stamped)

INSTRUCTIONS

GENERAL

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.1(b).
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mock-up of the proposed label. If prepared as a mock-up it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mock-up labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in three copies. In order to facilitate review, each type of data submitted must be bound separately, and clearly identified on the front cover including the data submitted.

A copy of the application form and a copy of the label should be bound in each separate volume of the data.

ALL DATA FOR WHICH CLAIMS OF CONFIDENTIALITY ARE ASSERTED MUST BE SUBMITTED, BOUND SEPARATELY AND CLEARLY MARKED AS SUCH.

SPECIFIC

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in BLOCK A, for which you are submitting this application. For applications submitted in connection with NEW REGISTRATION actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

BLOCK A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both REGISTRATION and AMENDED REGISTRATION actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant NOT residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

AMENDMENT INFORMATION

Section II - This Section must be completed for all applications submitted in connection with AMENDED REGISTRATION.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements", etc.

PACKAGING AND CONTAINER INFORMATION

Section III - This Section must be completed for all applications submitted in connection with NEW REGISTRATION.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the statement of net contents.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Direction** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

CONTACT POINT

Section IV - This Section must be completed for all REGISTRATION and AMENDED REGISTRATION applications.

1-5. Self-explanatory.

6. EPA Use Only.

EPA Form 8570-1 (Rev. 5-81) REVERSE



Ixodes Vector Control

Mr. George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
Environmental Protection Agency
401 M. Street SW
Washington, D.C. 20460

20 October, 1986

Dear Mr. LaRocca,

Two new tick-borne infections have emerged during the past decade as important public health threats involving large regions of the United States. The spirochete, *Borrelia burgdorferi* is responsible for a multisymptom disease complex (known as **Lyme disease**), while *Babesia microti* produces a malaria-like disease (known as **babesiosis**). **Lyme disease** has become the most prevalent tick-borne illness in the United States, as thousands of cases have occurred. Grave chronic complications may follow the more acute pathology associated with both of these diseases. Where infection is common, inapparent babesiosis influences blood bank policy because of the risk of transfusion-induced babesiosis. Clinical reports liken the delayed manifestations of **Lyme disease** to those of neurosyphilis. This demyelinating pathogen may produce symptoms that mimic those of multiple sclerosis and Alzheimer's disease. Miscarriage and grave birth defects may occur. The public health burden imposed by these infections has not yet been completely defined.

The ticks which transmit these disease-causing pathogens feed mainly on small rodents in their immature stages, but will attack a wide variety of potential hosts, including people. The principal natural reservoir for both pathogens is the white-footed mouse (*Peromyscus leucopus*). Larval ticks acquire infection during blood-feeding on this reservoir host, and both pathogens can be transmitted to another mouse, or to other hosts, by the resulting nymphal tick that feeds one year later. Because *P. leucopus* is both the most abundantly parasitized host, and serves as the principal reservoir for both pathogens, control strategies to reduce human disease can focus on this mouse.

The product, for which we are requesting registration, is highly effective at reducing the abundance of infective ticks, and constitutes a minimum threat

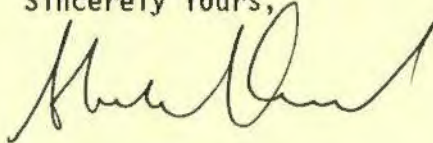
to the environment, the user, and the mice, when compared to spray or broadcast applications of a pesticide. Mice continuously collect nesting material throughout their home range (usually about 10 meters), and will also gather permethrin-impregnated cotton for this purpose. Thus, this proposed application of pesticide is highly focused at the target pest (ticks feeding on, and acquiring pathogens from, mice), and requires using less pesticide on a per acre basis than already approved for agricultural purposes. Application rates of permethrin to agricultural crops range from 0.05 to 0.2 pounds active per acre. The cotton dispensing tubes, when placed in an array every 10 meters as directed, total just 48 per acre. This is equivalent to using 0.04 pounds active permethrin per acre. This lower application rate, and the focused method of application, represents an environmentally safer and more target specific application than found in existing products.

It is our position that this product does not constitute a new use pattern, and therefore, can be reviewed by the Product Manager team. Permethrin-containing products are presently registered for agricultural applications, homeowner garden applications (including for use against fire ants), in-home applications (for control of numerous pests including fleas and ticks), and as a barn and livestock spray. Thus, the application of permethrin to mouse burrows does not constitute a new use pattern but instead simply represents a new application method.

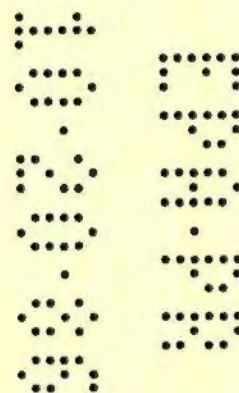
We do understand the workload at the agency, and the time-frames required to process an application. It is very important, however, that we make an application of the product by April, 1987, if we are to begin controlling Lyme disease and babesiosis this next year. This implies that registration is needed by early March, 1987. For this reason, should you find any deficiencies in this submission, or require additional data, please either call me directly, or contact Dr. Thomas Mather (617-732-2064) at the Harvard School of Public Health. He would best be able to answer any technical questions that may arise.

We thank you in advance for your consideration of this submission.

Sincerely Yours,



Alexander Kovel
President, IVC Corporation, Inc.



TICK BUSTER

EPA Reg. No.

EPA Est. No. 5693

A TICK AND FLEA TOXICANT

Permethrin-Impregnated Mouse Nest Material Kills Ticks and Fleas Attached to Mice and Present in the Nest

For the Control of Disease-Transmitting and Other Ticks and Fleas Around Yards and in Woodlots.

ACTIVE INGREDIENTS :

+* Permethrin 7.4%

INERT INGREDIENTS : 92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2-dichloroethenyl)-2,2-dimethyl cyclopropanecarboxylate

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans

KEEP OUT OF REACH OF CHILDREN

CAUTION

Statement of Practical Treatment

IF SWALLOWED- Contact a physician or Poison Control Center immediately. Drink one or two glasses of water and induce vomiting by touching back of the throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN- Remove contaminated clothing and wash affected areas with plenty of soap and water.

IF IN EYES- Flush eyes with plenty of water. Call a physician if irritation persists.

See side panel for additional precautionary statements.

Contents: 4.5 grams (approx. 30 cotton balls)

IVC Corporation, Inc., 33 Mt. Vernon Street, Boston, MA 02108

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY

For the control of ticks and other ectoparasites associated with rodents that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and transmit disease to humans, dogs and horses. The cotton balls enclosed in cardboard dispensing tubes are impregnated with Permethrin, and are intended as bedding that rodents will remove to their nests. Treatment of nests does not harm rodents, but kills disease-transmitting ticks, both on the rodents and in their nests.

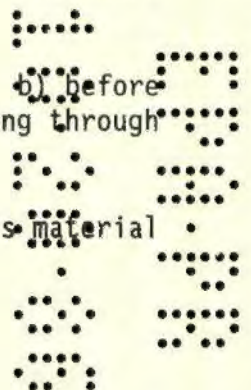
To apply, discard plastic end caps. For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 meters in any direction. Treatment should be limited to areas inhabited by rodents, and need not include mown lawns or open grasslands. Tubes should be positioned so that rodents have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 meter of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever rodents may reside. For complete coverage, all brush-covered or wooded areas within 50 meters surrounding the yard area to be protected should be treated. Replace tube when nesting material is completely removed.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 meters between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding woodlot. Placing tubes near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes should be applied at least twice a year: a) before April 1; b) before August 1. More frequent application, beginning in April and continuing through the summer will improve results.

NOTE: Do not remove cotton balls from inside of tube. Contact of this material with skin may cause irritation.



STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Store at room temperature. Do not expose to extreme temperatures or excessive sunlight.

PESTICIDE AND CONTAINER DISPOSAL: Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

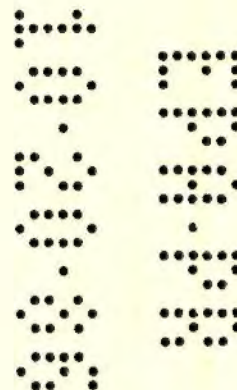
PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Remove and wash clothing before reuse. Avoid contamination of food and feed.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not apply to areas where contamination of fish bearing waters is likely. Do not contaminate water by disposal.



REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME

Permethrin - TICK BUSTER.

2. IDENTIFYING NUMBER

SL783-R

3. ACTION CODE

175

4. ACCESSION NUMBER

265659

TO BE COMPLETED BY PM

5. RECORD NUMBER

183,805

6. REFERENCE NUMBER

1

7. DATE RECEIVED (EPA)

10/30/86

8. STATUTORY DUE DATE

9. PRODUCT MANAGER (PM)

LaRocca/Dively

10. PM TEAM NUMBER

15

14. CHECK IF APPLICABLE

☒ Public Health/Quarantine

☐ Minor Use

☐ Substitute Chemical

☐ Part of IPM

☐ Seasonal Concern

☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS

12. PRIORITY NUMBER

13. PROJECTED RETURN DATE

15. INSTRUCTIONS TO REVIEWER

A. HED ☐ Total Assessment - 3(c)(5)
☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

C. ☐ BFSD
D. ☐ TSS/RD
E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)

☐ Chemical Undergoing Active RPAR Review
☐ Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

This is a new application method
for an old chemical. Please review
attached for adequacy to support
Sec. 3 registration.

16. RELATED ACTIONS

17. 3(c)(1)(D)

☐ Use Any or All Available Information ☐ Use Only Attached Data
☐ Use Only the Attached Data for Formulation and Any or All
☐ Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

☐ TB ☐ EEB ☐ EF ☐ PL
☐ RCB ☐ EFB ☐ CH ☐ BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20. ☐ Label Submitted with Application Attached

21. ☐ Confidential Statement of Formula

22. ☐ Representative Labels Showing Accepted Uses Attached

23. Date Returned to RD (to be completed by HED)

24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

171

Reg. # 56783 R
Rec. # _____

Product name _____

Tick Buster

PRODUCT CHEMISTRY CHECKLIST

Please provide the requested information for the following checked items:

1. ☐ Submit the product specific product chemistry and the data matrix for your product. Your product is not sufficiently similar to the product you referenced.
2. On the Confidential Statement of Formula (CSF) please provide the following:
 - ☐ a) Provide pH of product or pH at a specified water dilution.
 - ☐ b) density
 - ☐ c) flash point of product
 - ☐ d) flash point of product without the propellant.
 - ☐ e) flame extension
 - ☐ f) Provide the upper and lower Certified Limits based on the pure active ingredients rather than the technical or concentrate. Note that the lower limit of the active, including any solvent declared as active, must not fall below the label claim.
 - ☐ g) Provide upper and lower Certified Limits of the individually added inerts.
 - ☐ h)
 - ☐ i)
3. ☐ Based on the current CSF dated _____ your product will not meet the label claim for the active ingredient. Please revise the label or the CSF so the information agrees.
4. ☐ Please provide the chemical identity of the following:
 - 1)
 - 2)
 - 3)The supplier may contact us directly referencing your file symbol/EPA Reg. # in their response.
5. ☐ Please update the label Storage and Disposal Statement per PR 83-3 or PR 84-1.
6. ☐ Add a footnote to the label ingredient statement indicating: Contains petroleum distillates.
7. ☐ Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement. See attached sheet.
8. ☐ Since your data matrix does not give a dielectrical breakdown voltage, you must add the following to the use directions:
Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Cont'd next page

Reg. #

56783-L

CHEMISTRY CHECKLIST CONT'D

9. Data Matrix Requirements

- ☐ a) Statement of Composition - a complete description of the manufacturing/formulation process. Describe equipment used, mixing time, temperature etc.
- ☐ b) Discussion of Formation of [Unintentional] Ingredients - a brief description of impurities formed during the manufacturing/formulation process, in packaging, or during storage. If you do not expect any impurities during these stages, please so state.
- ☐ c) Certification of Limits - upper and lower limits of each active and individually added inert component. The lower limit for the actives, including solvents declared as active, must not fall below label claim.
- ☐ d) Analytical Methods - provide the methods used to analyze for the active ingredients.
- ☐ e) Color - in common terms.
- ☐ f) Physical State - solid, liquid or pressurized liquid
- ☐ g) Odor - in common terms.
- ☐ h) Density - e.g. lbs/gallon for liquids or lbs/cu. ft. for solids.
- ☐ i) pH - provide pH of product or pH of a specified water dilution.
- ☐ j) Oxidizing or Reducing - note these characteristics if any.
- ☐ k) Flammability - flash point/flame extension.
- ☐ l) Explosibility - note these characteristics if any.
- ☒ m) Storage Stability - the formulated product must be analyzed for its active ingredient at time zero and during a year of storage.
Note: For the Storage Stability study you cannot reference the concentrate you are using to formulate your product.
- ☐ n) Viscosity - can be expressed in centipoise or centistokes.
- ☐ o) Miscibility - note these characteristics if product is an emulsifiable liquid and mixed with oil.
- ☐ p) Corrosion Characteristics - this information can be noted during the storage stability study.
- ☐ q) Dielectric Breakdown Voltage - for products used near electrical equipment.

We need 1 yr Storage Stability
data -

If the Fairfield has submitted 4816-552
is some new CSF until it is approved
before you can't use this formulation - by
this comment you fact they should not have sold to
you - It is violation of the law
1/7/87
Bijan Goudh

IMPORTANT NOTE TO PM

- () The following standard comment must be forwarded to the registrant:

"The proposed formulation contains an ingredient for which some toxicological concerns have been raised. Therefore the formulation cannot be approved until the questions have been resolved."

- () The following must be added to section one given above:

"The ingredient of concern is contained in the xylylene fonyl Asomith which is proposed to be included in the formulation." extract in cone.

- () Since this product contains xylene and has directions for outdoor use, it must be forwarded to RSERB for referral to HED for review.

- () Under the new inert policy, since this product contains a undefined petroleum distillate, the following must be requested from the registrant: CAS number, flash point, boiling range, and the supplier spec. sheet if available.

The product contain toxic
inert list 2 for which SOP
will make decision on 1/31/87
hold until then & then
write a ltr

CERTIFICATION WITH RESPECT TO CITATION OF DATA

EPA FILE SYMBOL/REG. NO. _____ DATE OF APPLICATION October 20, 1986
 NAME OF PRODUCT TICK BUSTER
 APPLICANT'S NAME AND ADDRESS: IVC CORPORATION, INC
33 Mt. Vernon Street
Boston, MA 02108

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I have obtained the written permission of the original data submitter to cite that study.

3. I certify that, for each study cited in support of this application for registration that is NOT an exclusive use study:

I have obtained the written permission of the original data submitter to cite that study; OR

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c) (1) (D) and 3(c) (2) (D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirements of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (CHECK ONE)

☒ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method). (ALSO SIGN THE GENERAL OFFER TO PAY STATEMENT BELOW.)

☐ Those companies who have submitted the studies which I have cited (SELECTIVE METHOD)

DATE October 20, 1986

SIGNATURE _____

TITLE PRESIDENT

GENERAL OFFER TO PAY: I hereby offer and agree to any compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c) (1) (D) and 3(c) (2) (D).

DATE October 20, 1986

SIGNATURE _____

TITLE PRESIDENT

FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. _____ Product Name TICK BUSTER
Applicant's Name and Address IVC, CORPORATION, INC.
33 Mt. Vernon Street
Boston, MA 02108

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): _____
PERMETHRIN

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated _____ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

<u>Active ingredient</u>	<u>Source: Product name and Reg. No.</u>
_____	_____
_____	_____
_____	_____

Date 10/20/86

Signature

Title

PRESIDENT

DATA REQUIREMENT LISTING FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: TICK BUSTER <hr/> 5. APPLICANT'S NAME AND ADDRESS IVC Corporation, Inc. 33 Mt. Vernon Street Boston, MA 02108	2. EPA REG.NO/FILE SYMBOL <hr/> 6. APPLICATION FOR REGISTRATION DATED 10 / 20/86 Mo. Day Yr.	3. FORMULATOR'S EXEMPTION SELECTED YES <u> x </u> NO <u> </u> <hr/> 7. NAME OF ACTIVE INGREDIENT(S): PERMETHRIN	4. PAGE <u> 1 </u> of <u> 3 </u>
---	---	---	--

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER											
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or other (Explain)												
\$158.20	PRODUCT CHEMISTRY																		
61-1	Identity of ingredients	X	10/20/86																
61-2	Statement of composition	X	10/20/86																
61-3	Discussion of formation of ingredients	X	10/20/86																
62-1	Preliminary analysis						X												
62-2	Certification of limits	X	10/20/86																
62-3	Analytical methods for enforcement limits	X	10/20/86																
63-2	Color	X	10/20/86																
63-3	Physical state	X	10/20/86																
63-4	Odor	X	10/20/86																
63-5	Melting point						X												
63-6	Boiling point						X												
63-7	Density, bulk density, or specific gravity	X	10/20/86																

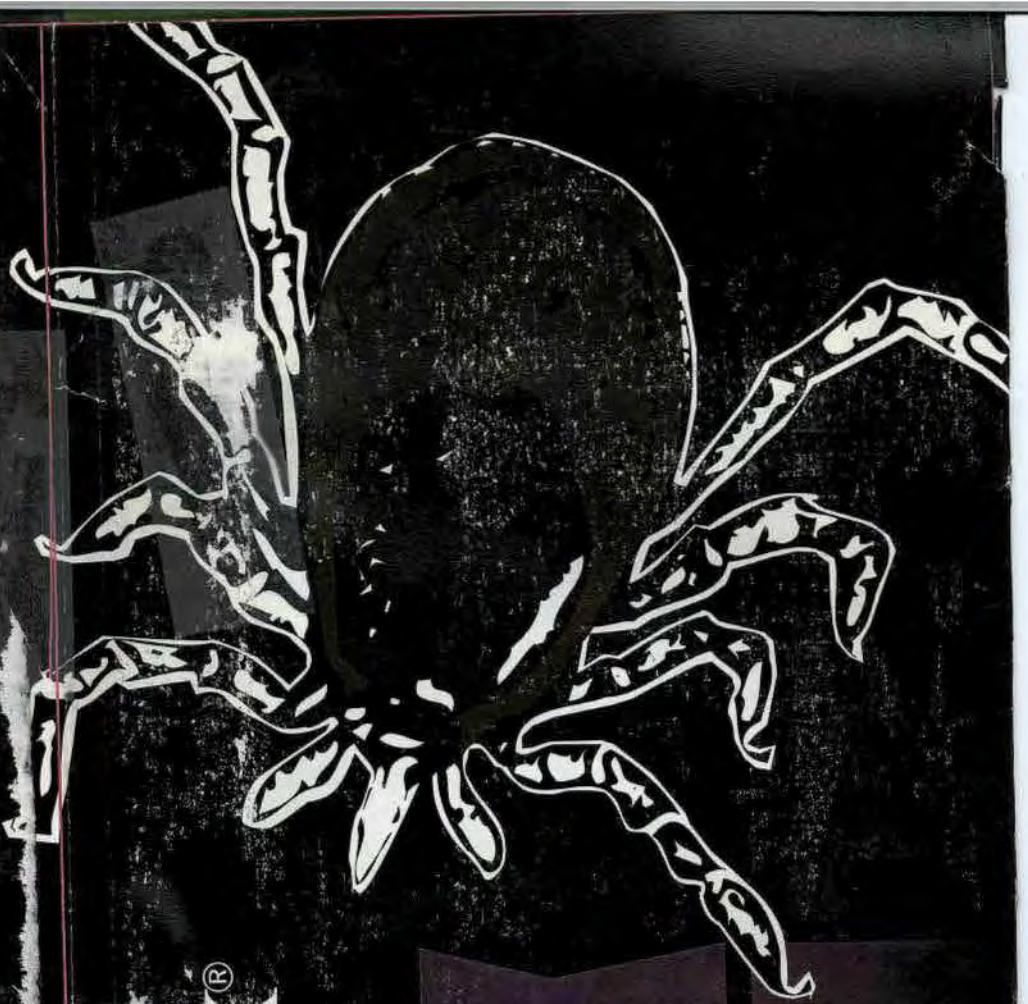
DATA REQUIREMENT LISTING FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: <u>TICK BUSTER</u> 5. APPLICANT'S NAME AND ADDRESS <u>IVC Corporation, Inc.</u> <u>33 Mt. Vernon Street</u> <u>Boston, MA 02108</u>	2. EPA REG.NO/FILE SYMBOL _____ 6. APPLICATION FOR REGISTRATION DATED <u>10 / 20 / 86</u> Mo. Day Yr.	3. FORMULATOR'S EXEMPTION SELECTED YES <u>X</u> NO _____ 7. NAME OF ACTIVE INGREDIENT(S): <u>PERMETHRIN</u>	4. PAGE <u>2</u> of <u>3</u>
--	--	--	------------------------------

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER			
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or other (Explain)				
\$158.20	PRODUCT CHEMISTRY (Continued)										
63-8	Solubility						X				
63-9	Vapor pressure						X				
63-10	Dissociation constant						X				
63-11	Octanol/water partition coefficient						X				
63-12	pH						X				
63-13	Stability						X				
63-14	Oxidizing/reducing reaction						X				
63-15	Flammability						X				
63-16	Explosibility						X				
63-17	Storage stability	X	10/20/86								
63-18	Viscosity						X				
63-19	Miscibility						X				

1. PRODUCT NAME: <u>TICK BUSTER</u> 5. APPLICANT'S NAME AND ADDRESS <u>IVC Corporation, Inc.</u> <u>33 Mt. Vernon Street</u> <u>Boston, MA 02108</u>	2. EPA REG.NO/FILE SYMBOL _____ 6. APPLICATION FOR REGISTRATION DATED <u>10 / 20 / 86</u> Mo. Day Yr.	3. FORMULATOR'S EXEMPTION SELECTED YES <u>X</u> NO _____ 7. NAME OF ACTIVE INGREDIENT(S): _____	4. PAGE <u>3</u> of <u>3</u>
--	--	---	------------------------------

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or other (Explain)	
\$158.20	PRODUCT CHEMISTRY (continued)							
63-20	Corrosion characteristics	X	10/20/86					
63-21	Dielectric breakdown voltage						X	
\$158.135	TOXICOLOGY							
81-1	Acute oral LD-50, rat	CITE	ALL					
81-2	Acute dermal LD-50	CITE	ALL					
81-3	Acute inhalation LC-50, rat	CITE	ALL					
81-4	Primary eye irritation, rabbit	CITE	ALL					
81-5	Primary dermal irritation	CITE	ALL					
81-6	Dermal sensitization	CITE	ALL					



Tubes

TICK

**USE AS AN AID
IN THE CONTROL
OF LYME DISEASE
CARRYING TICKS.**

DAVENVILLY[®]

IS THE
ACTIVE

**TICK
Tubes**



Easy to use.
Apply once in the
spring and once in
the summer.

*Place in brush, woodpiles, rock walls
and flower-beds. Do not treat lawns -
most ticks do not live on lawns.*

USE AS AN AID IN THE CONTROL OF LYME DISEASE CARRYING TICKS.



TICK Tubes

DAMMINIX®

USE AS AN AID IN THE
CONTROL OF LYME
DISEASE CARRYING TICKS.

U.S. Patent No. 4,882,104
ACTIVE INGREDIENT: Permethrin, 7.4% INERT INGREDIENTS: 92.6%

CAUTION: KEEP OUT OF REACH OF CHILDREN.
See bottom panel for precautions and first aid.

EPA Reg. No. 56783-1
EPA Est. No. 5693-MA-1

24 TUBES • TREATS APPROXIMATELY 22,000 SQ. FT.

DAMMINIX® A TICK TOXICANT As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, paths, and in woodlands.

EPA Reg. No. 56783-1

EPA Est. No. 5693-MA1

ACTIVE INGREDIENT: + * Permethrin

7.4%

INERT INGREDIENTS:

92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans-3-(2,2-dichloroethenyl)-2, 2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

CAUTION: KEEP OUT OF REACH OF CHILDREN

FIRST AID

INGESTION - If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

EXPOSURE, SKIN IRRITATION - If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

EYES - If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding the woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed.

STORAGE AND DISPOSAL: Store at room temperature. Do not contaminate water, food or feed by storage and disposal. Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS: Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS: This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by disposal of wastes or equipment washwaters.

© 2001, ECOHEALTH, INC. 33 MT. VERNON ST., BOSTON, MASSACHUSETTS 02108 617-742-2400 CONTENTS: 24 Damminix Tubes, each containing 4.5 grams.

USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

Tick Tubes



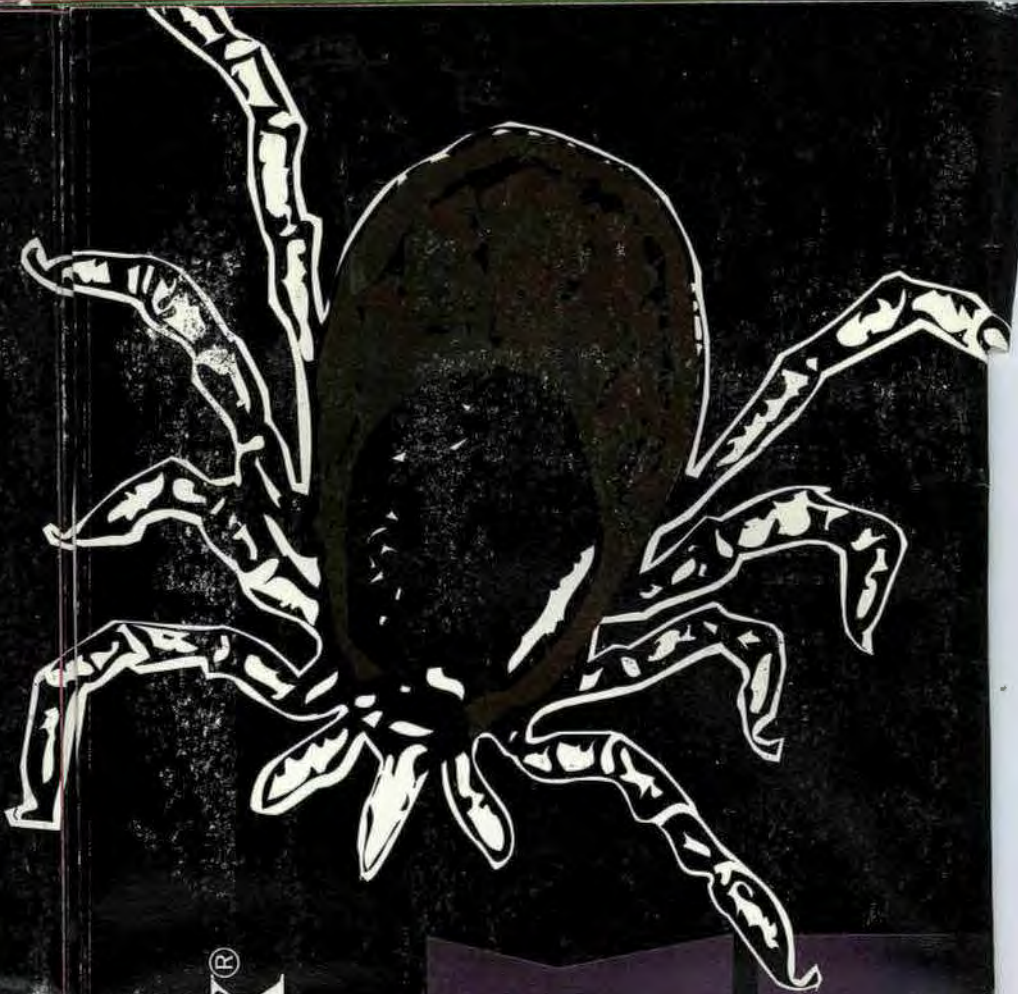
TREATS APPROXIMATELY
22,000 SQUARE FEET

USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

Tick Tubes

U.S. Forest Service
Active Release

TREATS APPROXIMATELY
22,000 SQUARE FEET



DAMMINIX[®]

TICK Tubes

USE AS AN AID
IN THE CONTROL
OF LYME DISEASE
CARRYING TICKS.



Easy to use.
Apply once in the
spring and once in
the summer.

Place in brush, woodpiles, rock walls
and flower-beds. Do not treat rooms.
most ticks do not live on lawns.

TICK Tubes

USE AS AN AID IN THE CONTROL OF LYME DISEASE CARRYING TICKS.



TICK

Tubes

USE AS AN AID IN THE
CONTROL OF LYME
DISEASE CARRYING TICKS.

CAUTION: KEEP OUT OF REACH OF CHILDREN.
See bottom panel for precautions and first aid.

EPA Reg. No. 56783-1
EPA Est. No. 5693 MA 1

U.S. Patent No. 4,862,104
ACTIVE INGREDIENT: Permethrin 7.4%, INERT INGREDIENTS 92.6%

24 TUBES • TREATS APPROXIMATELY 22,000 SQ. FT.

DAMMINIX® A TICK TOXICANT As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

EPA Reg. No. 56783-1

EPA Est. No. 5693 MA 1

ACTIVE INGREDIENT: + Permethrin

7.4%

INERT INGREDIENTS:

92.6%

Total 100.0%

+ (3-phenoxy(phenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethenyl)2, 2-dimethylcyclopropanecarboxylate.
* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS. Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding the woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed.

STORAGE AND DISPOSAL: Store at room temperature. Do not contaminate water, food or feed by storage and disposal. Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS. Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS: This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by disposal of wastes or equipment washwaters.

CAUTION: KEEP OUT OF REACH OF CHILDREN

FIRST AID

INGESTION - If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

EXPOSURE, SKIN IRRITATION - If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

EYES - If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

Tick Tubes



TREATS APPROXIMATELY
22,000 SQUARE FEET

USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

Tick Tubes

U.S. Patent No. 4,662,104
ACTIVE INGREDIENT: Permethrin, 7.4%

EPA Reg. No. 56783-1
EPA Est. No. 5693 MA 1

TREATS APPROXIMATELY
22,000 SQUARE FEET

Tick
Tubes

USE AS AN AID
IN THE CONTROL
OF LYME DISEASE
CARRYING TICKS.

DAVMINIX®

Tick
Tubes

Easy to use.
Apply once in the
spring and once in
the summer.

Place in brush, rodent holes and
and
ticks are on



USE AS AN AID IN THE CONTROL OF LYME DISEASE CARRYING TICKS.



TICK

DAMMINIX®

Tubes

USE AS AN AID IN THE
CONTROL OF THE
DISEASE CARRYING TICKS.

U.S. Patent No. 4,662,104

ACTIVE INGREDIENT: Permethrin 7.4%, INERT INGREDIENTS: 92.6%

CAUTION: KEEP OUT OF REACH OF CHILDREN.
See bottom panel for precautions and first aid.

EPA Reg. No. 56783-1
EPA Est. No. 5693 MA 1

24 TUBES • TREATS APPROXIMATELY 22,000 SQ. FT.

DAMMINIX® A TICK TOXICANT As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

EPA Reg. No. 56783-1

ACTIVE INGREDIENT: + * Permethrin

INERT INGREDIENTS:

EPA Est. No. 5693 MA1

7.4%

92.6%

Total 100.0%

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

CAUTION: KEEP OUT OF REACH OF CHILDREN

FIRST AID

INGESTION - If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

EXPOSURE, SKIN IRRITATION - If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

EYES - If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding the woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed.

STORAGE AND DISPOSAL: Store at room temperature. Do not contaminate water, food or feed by storage and disposal. Do not reuse empty tubes. The tubes and unused cotton are biodegradable and may be left in the application site. If disposal is desired, wrap tube and put in trash collection.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS: Avoid contact with eyes and skin. Contact with skin may result in temporary numbing and tingling sensations. Wash thoroughly with soap after handling.

ENVIRONMENTAL HAZARDS: This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by disposal of wastes or equipment washwaters.

USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

Tick Tubes



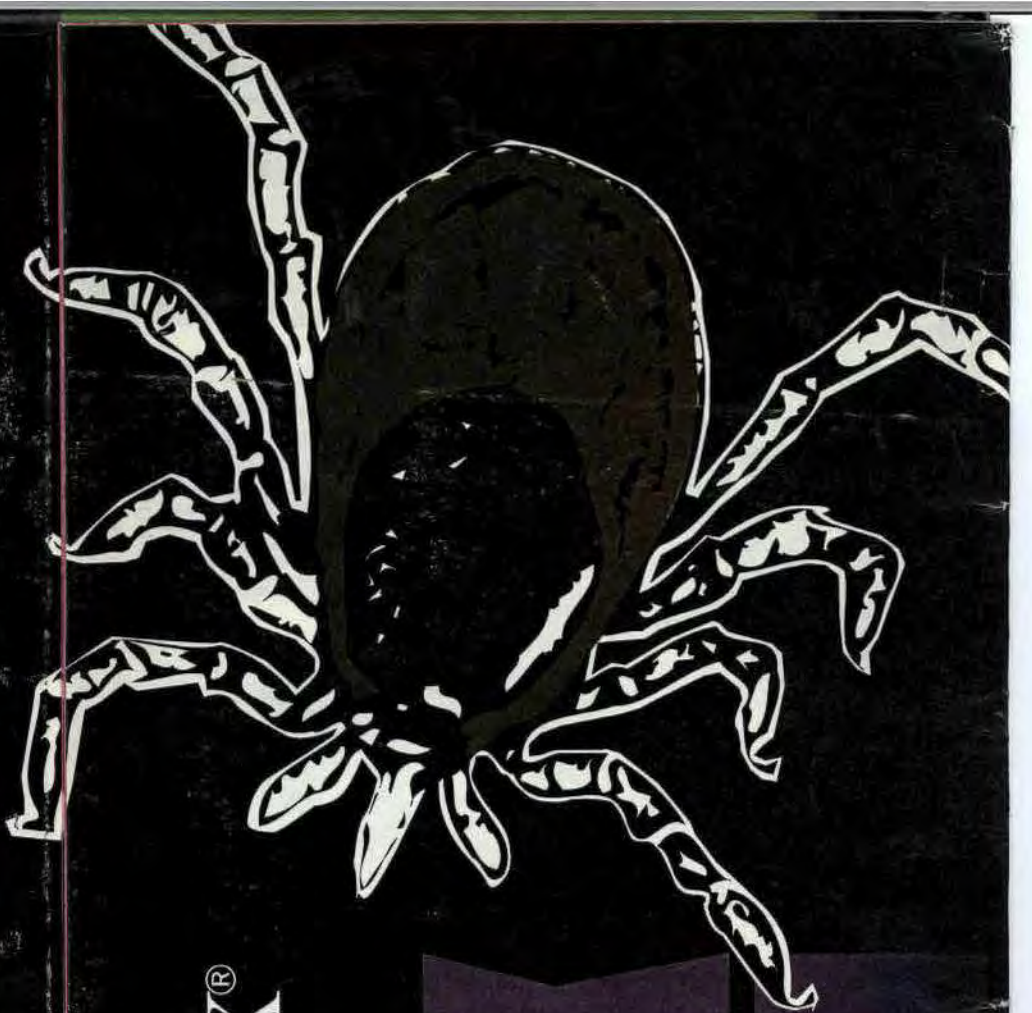
TREATS APPROXIMATELY
22,000 SQUARE FEET

U.S. Patent No. 4,592,704
ACTIVE INGREDIENT: Permethrin, 7.5%

EPA Reg. No. 35783-1
EPA Est. No. 5695-MA-1

Tick Tubes

TREATS APPROXIMATELY
22,000 SQUARE FEET



DAMMINIX[®]

Tick Tubes

USE AS AN AID
IN THE CONTROL
OF LYME DISEASE
CARRYING TICKS.



Tick Tubes



Easy to use.
Apply once in the
spring and once in
the summer.

Place in brush, woodpiles, rock walls
and flower beds. Treat lawn
most ticks do not live on lawns.

USE AS AN AID IN THE CONTROL OF LYME DISEASE CARRYING TICKS.



DAMMINIX®

TICK Tubes

USE AS AN AID IN THE
CONTROL OF LYME
DISEASE CARRYING TICKS.

U.S. Patent No. 4,662,104
ACTIVE INGREDIENT: Permethrin, 7.4%, INERT INGREDIENTS: 92.6%

CAUTION: KEEP OUT OF REACH OF CHILDREN.
See bottom panel for precautions and first aid.

EPA Reg. No. 56783-1
EPA Est. No. 5693 MA 1

24 TUBES • TREATS APPROXIMATELY 22,000 SQ. FT.

DAMMINIX® A TICK TOXICANT As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths, and in woodlands.

EPA Reg. No. 56783-1

ACTIVE INGREDIENT: + * Permethrin

INERT INGREDIENTS:

EPA Est. No. 5693 MA1

7.4%
92.6%

FOR OUTDOOR USE
DISEASE AND HAD

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

CAUTION ONLY: For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and had ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

+ (3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethyl)2, 2-dimethylcyclopropanecarboxylate.

* Cis/trans ratio: Min. 35% (+/-) cis and max. 65% (+/-) trans.

Total 100.0%

For best results
should not ex

at on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 feet. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

IN YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, in flower beds, and along fences, and in brush-covered areas. In woodlands, place tubes in brush-covered areas within 10 feet of the edge of the brush-covered area.

be placed in a contiguous array (such as a grid) and only tubes up to the brush-covered edge surrounding the area to be treated. Place more tubes in areas with more than those placed in more open woodland terrain.

September, but should be applied at least twice a year (August-September) ticks. Tubes may also be applied in areas where ticks are known to be present.

water, food or feed by storage and disposal site. If disposal is desired, wrap tubes in plastic and dispose of in a trash can.

with skin may result in irritation. Do not apply to children or pets.

UTION
FIRST

USE AS AN AID IN THE CONTROL OF
LYME DISEASE CARRYING TICKS.

Tick Tubes

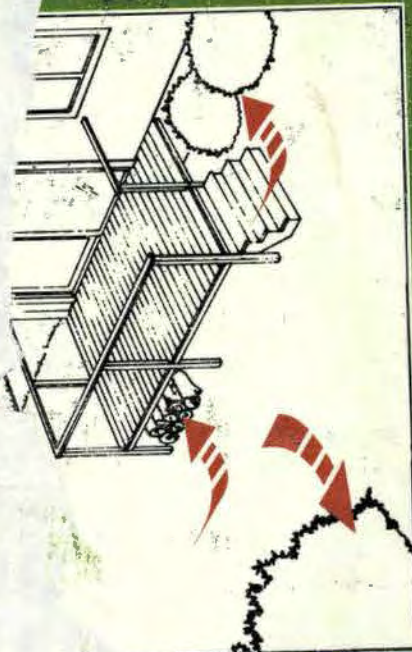


U.S. Patent No. 4,652,104
ACTIVE INGREDIENT: Permethrin, 7.4%

EPA Reg. No. 56783-1
EPA Est. No. 5893 MA-1

TREATS APPROXIMATELY
22,000 SQUARE FEET

TREATS APPROXIMATELY
22,000 SQUARE FEET



the sun

Place in brush, wood piles, rock walls
and flower beds to treat lawn
most ticks do not live on lawns

USE AS AN AID IN THE CONTROL OF LYME DISEASE CARRYING TICKS.